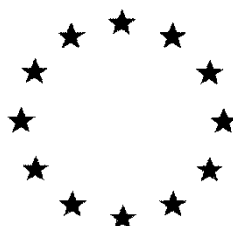


European Commission

**Second Programme for the Renewal of the Inclusion of Active Substances
in Annex I of Council Directive 91/414/EEC**



**Draft Renewal Assessment Report prepared according to the Commission
Regulation (EU) N° 1141/2010**

Amitrole

Volume 3 – Annex B.8

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Table of contents

B.8. ENVIRONMENTAL FATE AND BEHAVIOUR.....	3
SUMMARY OF USES AND PROPERTIES	3
B.8.1. ROUTE AND RATE OF DEGRADATION IN SOIL (ANNEX IIA 7.1.1, ANNEX IIIA 9.1.1).....	7
B.8.1.1. Route of degradation (annex IIA 7.1.1.1.).....	7
B.8.1.2. Rate of degradation (annex IIA 7.1.1.2).....	19
B.8.1.3. Summary on route and rate of degradation in soil.....	55
B.8.2. ADSORPTION, DESORPTION AND MOBILITY IN SOIL (ANNEX IIA 7.1.2 AND 7.1.3, ANNEX IIIA 9.1.2) .	58
B.8.2.1. Adsorption and desorption of the active substance (annex IIA 7.1.2).....	58
B.8.2.2. Adsorption and desorption of relevant metabolites (annex IIA 7.1.2).....	60
B.8.2.3. Column leaching studies (annex IIA 7.1.3).....	60
B.8.2.4. Aged residue column leaching (annex IIA 7.1.3.2).....	60
B.8.2.5. Lysimeter studies (annex IIA 7.1.3.3).....	61
B.8.2.6. Summary on the mobility of amitrole and its relevant metabolites in soil	61
B.8.3. PREDICTED ENVIRONMENTAL CONCENTRATIONS IN SOIL (PEC_s) (ANNEX IIIA 9.1.3).....	62
B.8.4. FATE AND BEHAVIOUR IN WATER (ANNEX IIA 7.2.1, ANNEX IIIA 9.2.1 AND 9.2.3)	64
B.8.4.1. Hydrolysis	64
B.8.4.2. Photodegradation in water	64
B.8.4.3. Biological degradation.....	64
B.8.4.4. Summary of degradation pathways and rates of amitrole in water.....	81
B.8.5. IMPACT ON WATER TREATMENT PROCEDURE (ANNEX IIIA 9.2.2).....	81
B.8.6. PREDICTED ENVIRONMENTAL CONCENTRATIONS IN GROUND WATER AND IN SURFACE WATER (PEC_{GW}, PEC_{SW}) (ANNEX IIIA 9.2.1 AND 9.2.3)	81
B.8.6.1. Predicted environmental concentrations in ground water.....	81
B.8.6.2. Predicted environmental concentrations in surface water	95
B.8.7. FATE AND BEHAVIOUR IN AIR (ANNEX IIA 7.2.2, ANNEX IIIA 9.3).....	110
B.8.7.1. Vapour pressure.....	110
B.8.7.2. Photolysis in air	110
B.8.7.3. Volatilisation from soil surface or plants.....	110
B.8.7.4. Summary of fate and behaviour in air	110
B.8.8. PREDICTED ENVIRONMENTAL CONCENTRATIONS IN AIR (PEC_A) (ANNEX IIIA 9.3).....	111
B.8.9. DEFINITION OF THE RESIDUE (ANNEX IIA 7.3)	111
B.8.10. MONITORING DATA (ANNEX IIA 7.4)	111
B.8.11. REFERENCES RELIED ON.....	117

B.8. ENVIRONMENTAL FATE AND BEHAVIOUR

This document was prepared for the re-assessment of Amitrole. Reference is made to the original DAR when no new data was submitted. However, at least a summary of the fate and behaviour of Amitrole in each compartment (soil, water and air) is reminded in this document.

SUMMARY OF USES AND PROPERTIES

The GAP are presented in the following table. It is noted that non crop uses are sustained. Non crop uses include a wide variety of uses, which can differ between Member States. A “standard” assessment for non-crop uses is provided in this document, but specific uses may need to be assessed at Member State level.

WARNING: This document forms part of an EC evaluation data package and should not be read in isolation. Registration may not be granted on the basis of this document.

Table 8.1.1-1: Proposed maximum use of Amitrole within the European Union

Crop and/ or situation (a)	Zone	Product code	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type	Conc. of a.s.	method kind	growth stage & season	number min max	interval between applications (min)	kg as/hL	water L/ha	kg as/ha		
					(d-f)	(i)	(f-h)	(j)	(k)		min max	min max	min max		
Orchards (citrus fruits, pome and stone fruits, assorted fruits- edible or inedible peel, tree nuts)	all MS	CA 2735	F	Non selective control of well developped annual and perennial monocotyledon es and dicotyledones weeds (growth stage 40-60)	solub le conc (SL)	229 g/L (HPLC)	broadcast spraying under the row or on localized areas with tractor mounted boom	94-75	1-2	2-3 months	1,2-3	300 to 500	0,24-1	35	CA2735 is applied either once per year at 2977 gai/ha or several times at lower rates but respecting the maximum application rate /year of 3000 gai/ha/year. A split application technique is possible at lower rates especially in case of mixture with foliar or residual herbicide according to the crop.
Grapes (table and vine)	all MS	CA 2735	F	Non selective control of well developped annual and perennial monocotyledon es and dicotyledones weeds (growth stage 40-60)	solub le conc (SL)	229 g/L (HPLC)	broadcast spraying under the row or on localized areas with tractor mounted boom	92-79	1-2	2-3 months	1,2-3	300 to 500	0,24-1	42	CA2735 is applied either once per year at 2977 gai/ha or several times at lower rates but respecting the maximum application rate /year of 3000 gai/ha/year. A split application technique is possible at lower rates especially in case of mixture with foliar or residual herbicide according to the crop.

Crop and/ or situation (a)	Zone	Product code	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type	Conc. of a.s.	method kind	growth stage & season	number min max	interval between applications (min)	kg as/hL	water L/ha	kg as/ha		
					(d-f)	(i)	(f-h)	(j)	(k)		min max	min max	min max		
Olives	south EU MS	CA 2735	F	Non selective control of well developped annual and perennial monocotyledon es and dicotyledones weeds (growth stage 40-60)	solub le conc (SL)	229 g/L (HPLC)	broadcast spraying under the row or on localized areas with tractor mounted boom	spring and autumn	1-2	2-3 months	0,9-1,375	300 to 500	0,18-0,5	35	CA2735 is applied either once per year at 2977 gai/ha or several times at lower rates but respecting the maximum application rate /year of 3000 gai/ha/year. A split application technique is possible at lower rates especially in case of mixture with foliar or residual herbicide according to the crop.
Non crop uses (impermea ble and permeable surfaces: road, railways)	all MS	CA 2735	F	Non selective control of well developped annual and perennial monocotyledon es and dicotyledones weeds (growth stage 40-60)	solub le conc (SL)	229 g/L (HPLC)	overall treatment for railways, roadsides, industrial areas with train/truck- mounted boom	Not applicable	1-2	2-3 months	1,8-3	300 to 500	0,36-1	–	CA2735 is applied either once per year at 2977 gai/ha or several times at lower rates but respecting the maximum application rate /year of 3000 gai/ha/year. A split application technique is possible at lower rates especially in case of mixture with foliar or residual herbicide according to the crop.

Crop and/ or situation (a)	Zone	Product code	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type	Conc. of a.s.	method kind	growth stage & season	number min max	interval between applications (min)	kg as/hL	water L/ha	kg as/ha		
					(d-f)	(i)	(f-h)	(j)	(k)		min max	min max	min max		

Remarks:

- (a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
- (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
- (c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
- (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
- (e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
- (f) All abbreviations used must be explained
- (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
- (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated

(i) g/kg or g/l

(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application

(k) The minimum and maximum number of application possible under practical conditions of use must be provided

(l) PHI - minimum pre-harvest interval

(m) Remarks may include: Extent of use/economic importance/restrictions

B.8.1. ROUTE AND RATE OF DEGRADATION IN SOIL (ANNEX IIA 7.1.1, ANNEX IIIA 9.1.1)**B.8.1.1. Route of degradation (annex IIA 7.1.1.1.)****B.8.1.1.1. Aerobic degradation**

Two studies (Hawkins *et al.*, 1982a; Scholz *et al.*, 1988) had been provided in the original DAR to define the route of degradation of amitrole in soils. These studies had been considered acceptable and are not re-assessed by RMS. However, RMS reminds that some deviations had been identified, the main ones being:

- For Hawkins *et al.*, 1982a: Volatiles were measured in separated experiments. Therefore, in the experiments presenting the distribution of applied radioactivity, no mass balance can be done.
- For Scholz *et al.*, 1988: the incubation period was very short (1 to 5 days) and measurements were performed only at the end of the incubation period.

No new standard study according to OECD 307 was submitted. However, when recalculating the DT50 of amitrole, the applicant made reference to the study of Hall (1994). RMS noted that this study, although dated 1994, was not included in the original DAR. Therefore, it is summarised below under B.8.1.1.1.1.

Additional data from a PhD thesis and from a related scientific publication were also provided by the applicant. An overall summary of both documents is presented under B.8.1.1.1.2.

B.8.1.1.1.1. Aerobic degradation of Amitrole in one sandy soil

Hall, B.E., 1994 – The aerobic degradation of radiolabelled amitrole in soil. Report No 10526.

- ❑ **Guidelines:** USEPA 162-2
- ❑ **GLP:** Yes
- ❑ **Deviations:** Some radioactivity remains unidentified
- ❑ **Acceptability:** Yes
- ❑ **Method**

The objective of this study was to investigate the route and rate of degradation of [3-¹⁴C]-amitrole (specific activity 228 µCi/mg, radiochemical purity 98%) under aerobic conditions at nominal temperature of 7 and 22°C in one soil after one application at 8 mg/kg.

Full characteristics of the soil used are presented in the following table. This soil was freshly collected from topsoil. On receipt, it was passed through a 2mm sieve. Prior to use, it was stored in the dark at *ca.* 4°C under aerobic conditions.

Table 8.1.1-1: Soil characteristics

Texture	Sand
Sand (%)	87.81
Silt (%)	9.16
Clay (%)	3.02
Organic Matter (%)	0.91
CEC (meq/100 g)	2.25
pH (water)	6.2
Moisture at 0.33 bar (%)	10.15
Microbial analysis (TVB)	
Aerobic bacteria	2.23 x 10 ⁶
Aerobic spores	1.32 x 10 ⁵
Anaerobic bacteria	1.18 x 10 ⁶
Anaerobic spores	8.75 x 10 ³

TVB: Total Viable Bacteria

Samples of soil (100 g over dry weight equivalent) were weighed into individual Erlenmeyer flasks and allocated as detailed in the following table.

Table 8.1.1-2: Test systems

Group	Flasks	No. of incubates	Soil conditions	Treatment	Incubation temperature and lighting	Composition of $^{14}\text{CO}_2$ absorbent	Sampling intervals
A	1-32	32*	Viable	[^{14}C]-Amitrole	$22 \pm 2^\circ\text{C}$, dark	Individual; ethanolamine	0, 8h, 1, 3, 5, 7, 10, 14, 21 and 30 days, 8, 13, 26, 39 and 52 weeks
B	33-36	4	Viable	[^{14}C]-Amitrole	$22 \pm 2^\circ\text{C}$, dark	Individual; NaOH	13 and 52 weeks
C	37-44	8	Sterile	[^{14}C]-Amitrole	$22 \pm 2^\circ\text{C}$, dark	Individual; ethanolamine	30 d, 13, 26 and 52 weeks
D	45-61	17*	Viable	[^{14}C]-Amitrole	$7 \pm 2^\circ\text{C}$, dark	Bulk; ethanolamine	0, 8h, 1, 3, 5, 7, 10, 14, 21 and 30 days, 8, 13, 26, 39 and 52 weeks
E	62-65	4	Viable	Amitrole	$22 \pm 2^\circ\text{C}$, dark	None	TVB analysis, 13, 26 and 52 weeks
F	Group F1-6	6*	Viable	Amitrole	$7 \pm 2^\circ\text{C}$, dark	None	TVB analysis, 13, 26 and 52 weeks

* Includes 2 contingency incubations

All samples were maintained under the proposed conditions for *ca* 5 weeks prior to dose administration. A target weight for each incubate at 75% moisture holding capacity at 0.33 bar was calculated. The moisture content of each sample was adjusted gravimetrically to, and maintained at, approximately this moisture level. Samples in study group C were sterilized by autoclaving on 2 occasions (4 weeks and 1 week) prior to dose administration.

Dose formulation (1 mL), containing a nominal 0.8 mg of ^{14}C -amitrole was applied evenly to the surface of each soil sample from study groups A, B, C and D. Application to those sterilized soil samples in study group C was conducted in a laminar flow cabinet using aseptic techniques. Triplicate aliquots of formulation were taken on 3 occasions during application to study groups A, B and C and on 2 occasions during application to study group D. Each aliquot was transferred to a volumetric flask, diluted with methanol and the radioactive content determined by LSC. The radioactive application rates to groups A, B and C was 14.5 μCi ; the corresponding value for group D was 14.7 μCi . Dose formulation (1 mL) containing 0.8 mg of non radiolabelled amitrole was similarly applied to groups E and F.

The contents of all incubation flasks were gently tumbled immediately following dose application.

Following application, all flasks were weighed and if necessary the moisture content adjusted. With the exception of zero-time samples, the flasks were connected to a continuous air-flow system set up as follows:

- Group A: air was introduced into each flask via an inlet glass manifold. The air entering the inlet manifold had been passed through soda lime to remove CO_2 and water to moisten the air. The inflowing air was passed over the surface of each soil sample. The gas mixture leaving each flask was passed through a safety trap then ethanediol (*ca* 50 g) and ethanolamine (2 x *ca* 50 g) to trap any liberated volatiles and carbon dioxide respectively. On leaving the final trap, the air was passed into an outlet manifold the outlet of which was attached to a suction pump. The following modification were introduced by study group:
- Group B: 0.2 M sodium hydroxide was used in place of ethanolamine.
- Group C: The air entering and leaving the flasks was passed through in-line sterile filters (pore size : 0.2 μm) in order to maintain sterile conditions.
- Group D: The gas mixtures leaving the flasks were combined before being passed through an array of traps similar, but larger in volume to those described for Group A. Following application of the test material formulation, the in-flowing water bottle was removed from Group D (and F) apparatus in order to facilitate a reduction in the soil moisture content.
- Group E & F: The gas mixture leaving the flasks was passed through a safety trap only.

Flow rates through individual representative flasks were measured periodically. During the course of this study, flow rates of between 30-80 mL/min were recorded. Where flow rates were low (< ca 50 mL/min), appropriate corrective action was taken to increase the rates to an optimum of 50-70 mL/min.

The contents of each trap were replenished and analysed at weekly intervals up to 8 weeks, then at 2 weekly intervals up to 26 weeks (30 weeks for group D) and at 4 weekly intervals thereafter; trap contents were also analysed for each incubate at the time of removal of the incubation flask. Trap collection and/or replenishment were conducted within 1 day of the scheduled interval. The radioactive content of each trap was determined by LSC.

Duplicate (groups A and C) or single (group D) incubation flasks were removed for analysis at those intervals identified in the above table. For group B, the incubation flasks were removed from the aeration system as described above but their contents were not analysed; the trap contents from this study group were analysed for total radioactive content throughout the incubation period. The contents of the flasks in Group E and F were used for TVB analysis.

Throughout the incubation period, flasks in Group A, B, C and E were maintained within the temperature range 20-24.5°C with the exception of 2 occasions. On one occasion a temperature of 18.5°C was recorded (no longer than 8 hours). On the second occasion, a temperature (minimum) of 16.5°C was noted (no longer than 12 hours). Samples in groups D and F were maintained at 4.6-9.9°C during incubation. All samples were incubated in the dark at a moisture content of ca 75% of that determined at 0.33 bar.

Following removal from the aeration system, each soil sample from groups A, C, D was quantitatively transferred to an amberlite jar and ethanol:water (1:1, by volume) added. The sample was shaken on a wrist action shaker for ca 1 hr and the supernatant removed following centrifugation (1000 or 1500 r.p.m. for 15 min). A total of 3 such extractions were conducted on each sample. The radioactive content of each extract was determined by LSC. 2 further extractions were conducted on the remaining residues from 2 selected samples (zero-time, flask 2 and 7 day, flask 12) from group A. The 2 extractants used were:

- 4th extraction: ethanol:water (1:1, by volume) adjusted to pH 2.5 with 1 M HCl
- 5th extraction: methanol:acetone:water (1:1:1, by volume) adjusted to pH 2.5 with 1 M HCl.

The radioactive content of each residue after extraction was determined following combustion.

Following combustion analysis, the residues from samples in Groups A and C were further extracted with ethanol for ca 24h under Soxhlet conditions. The radioactive content of the Soxhlet extracts was determined by LSC. Following Soxhlet extraction, the resultant residue from flask 12 was further extracted with extractant 6 (0.01 M potassium bromide in methanol:water (80:20, by volume)).

The pattern of radiolabelled degradates in soil extracts from Groups A, C and D was investigated by HPLC and TLC. It is noted that the following reference standards are available: Amitrole, urazole, aminoguanidine bicarbonate, cyanamid, 3-amino-5-one-1,2,4-triazole and 1,2,4-triazole.

□ Findings

Results are reported in the following tables.

Table 8.1.1-3: Percentage recovery (% AR) of radioactivity following application of ^{14}C -amitrole – Group A (22°C, viable)

Incubation time	Flask No	Extractable ^{14}C					Unextractable ^{14}C	Organic volatiles	$^{14}\text{CO}_2$	Apparatus wash	Total recovery
		Ethanol:water 1	Ethanol:water 2	Ethanol:water 3	Soxhlet	Total					
0 d	1	49.99	20.70	7.59	8.29	86.57	4.54	NS	NS	0.08	91.19
	2 ^a	48.56	23.11	7.85	2.05	90.34	3.28	NS	NS	0.05	93.67
	Mean	49.28	21.91	7.72	nc	88.46	3.91	-	-	0.07	92.43
8 h	3	44.57	24.27	10.11	6.26	85.22	3.84	0.00	0.29	0.02	89.36
	4	43.43	25.13	10.54	9.02	88.12	2.92	0.00	0.29	0.01	91.34
	Mean	44.00	24.70	10.33	7.64	86.67	3.38	0.00	0.29	0.02	90.35
1 d	5	44.17	23.87	9.14	10.03	87.21	4.36	0.00	0.72	0.03	92.32
	6	41.63	25.67	9.89	10.48	87.67	3.55	0.00	0.70	0.04	91.96
	Mean	42.90	24.77	9.52	10.26	87.44	3.96	0.00	0.71	0.04	92.14
3 d	7	41.53	21.12	9.89	8.13	80.67	8.40	0.00	1.04	1.01	91.12
	8	47.22	21.46	7.21	6.72	82.61	7.55	0.00	1.30	0.80	92.26
	Mean	44.38	21.29	8.55	7.43	81.64	7.98	0.00	1.17	0.91	91.69
5 d	9	36.01	21.65	8.86	12.06	78.58	9.14	0.00	2.71	0.08	90.51
	10	37.03	21.30	8.52	12.30	79.15	8.79	0.00	2.84	0.09	90.87
	Mean	36.52	24.48	8.69	12.18	78.87	8.96	0.00	2.78	0.09	90.69
7 d	11	34.37	20.02	7.27	14.20	75.86	10.84	0.00	3.48	0.17	90.35
	12 ^b	31.53	21.10	7.24	4.28	74.13	12.92	0.00	4.00	0.09	91.14
	Mean	32.95	20.56	7.26	nc	75.49	11.88	0.00	3.74	0.13	90.75
10 d	13	29.79	19.92	7.71	14.55	71.97	15.78	0.00	5.84	0.12	93.71
	14	29.49	19.45	7.09	13.32	69.35	16.38	0.00	6.62	0.10	92.45
	Mean	29.64	19.69	7.40	13.94	70.66	16.08	0.00	6.23	0.11	93.08
14 d	15	26.79	17.49	8.88	10.68	63.84	19.59	0.01	7.78	0.10	91.32
	16	24.72	17.61	9.25	10.70	62.28	22.58	0.05	7.46	0.27	92.64
	Mean	25.76	17.55	9.07	10.69	63.06	21.09	0.03	7.62	0.19	91.98
21 d	17	21.10	14.08	6.68	9.14	51.00	28.67	0.04	14.69	0.23	94.63
	18	21.29	15.46	7.65	10.37	54.77	23.46	0.02	12.98	0.17	91.40
	Mean	21.20	14.77	7.17	9.76	52.89	26.07	0.03	13.84	0.20	93.02
30 d	19	16.71	10.84	5.57	10.52	43.64	28.26	0.02	20.72	0.05	92.67
	20	16.16	11.75	5.57	10.75	44.23	29.35	0.00	21.24	0.03	94.85
	Mean	16.44	11.30	5.57	10.64	43.94	28.81	0.01	20.98	0.04	93.77
8 w	21	6.80	5.42	2.02	1.50	15.74	32.84	0.09	35.35	1.88	86.00 ^c
	22	5.16	4.90	2.70	1.54	14.30	42.92	0.02	37.15	0.05	94.44
	Mean	5.98	5.16	2.36	1.52	15.02	37.93	0.06	36.25	0.97	90.22
13 w	23	1.08	2.21	2.98	2.28	8.55	40.89	0.06	44.50	0.01	94.01
	24	1.12	3.06	3.02	1.89	9.09	41.16	0.04	46.36	0.01	96.66
	Mean	1.10	2.64	3.00	2.09	8.82	41.03	0.05	45.43	0.01	95.34
26 w	25	0.54	0.76	0.19	1.19	2.68	42.27	0.16	51.97	0.06	97.14

	26	0.75	1.27	0.21	1.23	3.46	40.08	0.00	53.34	0.08	96.96
	Mean	0.65	1.02	0.20	1.21	3.07	41.18	0.08	52.66	0.07	97.05
39 w	27	0.65	2.34	1.50	0.72	5.21	34.44	0.22	55.61	0.00	95.48
	28	0.85	1.73	0.36	0.67	3.61	35.00	0.04	56.81	0.00	95.46
	Mean	0.75	2.04	0.93	0.70	4.41	34.72	0.13	56.21	0.00	95.47
52 w	29	0.86	1.05	1.54	0.54	3.98	39.20	0.21	58.58	0.03	102.00
	30	0.83	1.07	0.87	0.77	3.55	36.10	0.05	58.20	0.04	97.94
	Mean	0.85	1.06	1.21	0.66	3.77	37.65	0.13	58.39	0.04	99.97

NE: Not Extracted

nc: not calculable

^a Additional extractions were performed for this sample. Extractions 4 and 5 before Soxhlet extraction gave respectively 5.80 and 2.97% AR. Total extractable ¹⁴C includes these values.^b Additional extractions were performed for this sample. Extractions 4 and 5 before Soxhlet extraction gave respectively 6.44 and 3.54% AR. Extractions 6 after Soxhlet extraction gave 0.99% AR. Total extractable ¹⁴C includes values from extractions 4 and 5.^c A proportion of the soil residue was lost during extraction**Table 8.1.1-4: Percentage recovery (% AR) of radioactivity in NaOH traps following application of ¹⁴C-amitrole – Group B (22°C, viable)**

Flask	Duration of incubation	Percentage of applied radioactivity in NaOH traps
33	13 weeks	40.45
34		40.27
35	52 weeks	50.94
36		45.93

Table 8.1.1-5: Percentage recovery (% AR) of radioactivity following application of ^{14}C -amitrole – Group C (22°C, sterile)

Incubation time	Flask No	Extractable ^{14}C			Unextractable ^{14}C	Organic volatiles	$^{14}\text{CO}_2$	Apparatus wash	Total recovery
		Ethanol:water	Soxhlet	Total					
30 d	37	56.02	16.76	72.78	17.35	0.00	0.01	0.24	90.38
	38	54.46	20.08	74.54	16.40	0.00	0.01	0.23	91.18
	Mean	55.24	18.42	73.66	16.87	0.00	0.01	0.24	90.78
13 w	39	35.73	14.01	49.74	38.23	0.00	0.04	0.09	88.10
	40	35.64	14.15	49.79	45.43	0.00	0.04	0.10	95.36
	Mean	35.69	14.08	49.77	41.83	0.00	0.04	0.10	91.73
26 w	41	18.23	13.93	32.16	59.37	0.00	0.25	0.06	91.84
	42	19.51	19.77	39.28	46.76	0.00	0.16	0.08	86.28
	Mean	18.87	16.85	35.72	53.07	0.00	0.21	0.07	89.06
52 w	43	18.35	10.13	28.48	57.76	0.01	1.56	0.09	87.90
	44	19.97	9.75	29.72	53.20	0.01	0.66	0.05	83.64
	Mean	19.16	9.94	29.10	55.48	0.01	1.11	0.07	85.77

Table 8.1.1-6: Percentage recovery (% AR) of radioactivity following application of ^{14}C -amitrole – Group D (7°C, viable)

Incubation time	Flask No	Extractable ^{14}C			Unextractable ^{14}C	Organic volatiles	$^{14}\text{CO}_2$	Apparatus wash	Total recovery
		Ethanol:water	Soxhlet	Total					
0 d	45	79.27	9.39	88.66	5.62	NS	NS	0.06	94.34
8 h	46	78.76	5.85	84.61	6.43		0.03	0.29	91.36
1 d	47	77.43	11.09	88.52	2.55		0.08	0.33	91.48
3 d	48	76.57	6.20	82.77	2.50		0.26	0.60	91.13
5 d	49	68.35	16.39	84.74	3.99		0.46	0.11	89.30
7 d	50	70.69	12.02	82.71	9.26	0.03	0.65	0.06	92.71
10 d	51	69.19	17.43	86.62	5.88	0.04	0.98	0.19	93.71
14 d	52	71.89	11.91	83.80	9.86	0.04	1.47	0.12	95.29
21 d	53	63.02	15.08	78.10	14.80	0.04	2.53	0.16	95.63
30 d	54	58.88	14.46	73.34	13.72	0.06	3.98	0.08	91.18
8 w	55	52.81	8.37	61.18	23.25	0.06	8.81	0.07	93.37
13 w	56	37.48	14.02	51.50	26.84	0.06	17.23	0.11	95.74
26 w	57	10.18	10.85	21.03	41.01	0.06	32.80	0.40	95.30
39 w	58	8.42	7.97	16.39	37.25	0.91	40.39	0.02	94.96
52 w	59	4.69	4.06	8.75	40.82	0.91	44.17	0.02	94.67

NS: not sampled

Table 8.1.1-7: TLC analysis (% AR) of soil extracts (aqueous ethanol extracts + soxhlet extracts) following application of ¹⁴C-amitrole – Group A (22°C, viable)

Incubation time	Flask No	Amitrole	Degradate B	Degradate C	Unidentified calculated by RMS ^b
0 d	1	73.78	ND	ND	12.79
	2 ^a	74.80 ^a	0.05	ND	6.72
	Mean	NC	NC	-	-
8 h	3	77.81	0.18	ND	7.23
	4	74.01	0.52	ND	13.59
	Mean	75.91	0.35	-	-
1 d	5	74.71	ND	ND	12.5
	6	81.92	ND	ND	5.75
	Mean	78.32	-	-	-
3 d	7	71.99	0.09	ND	8.59
	8	70.50	0.72	ND	11.39
	Mean	71.25	0.41	-	-
5 d	9	70.89	ND	ND	7.69
	10	72.02	ND	ND	7.13
	Mean	71.46	-	-	-
7 d	11	66.88	0.75	ND	8.23
	12 ^b	62.08 ^a	1.00	ND	1.07
	Mean	64.48	0.88	-	-
10 d	13	65.79	ND	ND	6.18
	14	63.62	0.52	ND	5.21
	Mean	64.71	0.26	-	-
14 d	15	57.33	0.82	ND	5.69
	16	58.58	0.80	ND	2.9
	Mean	57.96	0.81	-	-
21 d	17	42.81	1.61	ND	6.58
	18	46.36	2.09	ND	6.32
	Mean	44.59	1.85	-	-
30 d	19	35.53	2.46	ND	5.65
	20	31.78	5.65	ND	6.8
	Mean	33.66	4.06	-	-
8 w	21	8.08	3.07	0.28	4.31
	22	5.77	3.13	0.28	5.12
	Mean	6.93	3.10	0.28	-
13 w	23	2.74	1.95	ND	3.86
	24	2.36	2.20	0.19	4.34
	Mean	2.55	2.08	0.10	-
26 w	25	0.94	0.88	ND	0.86
	26	0.94	1.17	ND	1.35
	Mean	0.94	1.03	-	-
39 w	27	0.49	2.34	ND	2.38
	28	0.44	1.74	ND	1.43
	Mean	0.47	2.04	-	-
52 w	29	0.53	2.12	ND	1.33
	30	0.28	2.09	ND	1.18
	Mean	0.41	2.11	-	-

^a Total value excludes % amitrole in 4th and 5th cold extractions.^b Calculated from Total extractable (ethanol:water extractions 1 to 3 + soxhlet extraction) – (Amitrole + Degradates B and C)

ND: not detected

NC: not calculable due to prior extraction of samples 2 and 12 with extractants 4 and 5

Table 8.1.1-8: HPLC analysis (% AR) of soil extracts (aqueous ethanol extracts) following application of ¹⁴C-amitrole – Group A (22°C, viable)

Incubation time	Flask No	Amitrole	Degradate D	Degradate E	Degradate F	Unidentified calculated by RMS ^a
0 d	1	66.34	ND	ND	ND	11.94
	2 ^a	73.40	ND	ND	ND	6.12
	Mean	69.87	-	-	-	9.04
8 h	3	73.63	ND	ND	ND	5.32
	4	65.74	ND	ND	ND	13.36
	Mean	69.69	-	-	-	9.34
1 d	5	65.18	ND	ND	ND	12
	6	70.87	ND	ND	ND	6.32
	Mean	68.03	-	-	-	9.16
3 d	7	54.93	ND	ND	ND	17.61
	8	65.06	ND	ND	ND	10.83
	Mean	65.00	-	-	-	9.22
5 d	9	59.57	ND	ND	ND	6.95
	10	60.48	ND	ND	ND	6.37
	Mean	60.03	-	-	-	9.66
7 d	11	54.30	ND	ND	ND	7.36
	12 ^b	50.78	ND	ND	ND	9.09
	Mean	52.54	-	-	-	8.23
10 d	13	52.49	ND	ND	ND	4.93
	14	51.58	ND	ND	ND	4.45
	Mean	52.04	-	-	-	4.69
14 d	15	48.59	0.77	ND	ND	3.8
	16	48.30	1.49	ND	ND	1.79
	Mean	48.45	1.13	-	-	2.8
21 d	17	35.57	0.67	ND	ND	5.62
	18	38.53	ND	ND	ND	5.87
	Mean	37.05	0.34	-	-	5.75
30 d	19	27.43	1.05	ND	ND	4.64
	20	26.86	1.08	ND	ND	5.54
	Mean	27.15	1.07	-	-	5.09
8 w	21	9.16	1.05	ND	ND	4.03
	22	7.63	0.44	ND	ND	4.69
	Mean	8.40	0.75	-	-	4.35
13 w	23	1.70	0.29	0.16	ND	4.12
	24	2.21	0.44	0.48	ND	4.07
	Mean	1.96	0.37	0.32	-	4.09
26 w	25	0.68	0.22	0.07	0.05	0.47
	26	0.67	0.32	0.12	0.14	0.98
	Mean	0.68	0.27	0.10	0.10	0.72
39 w	27	0.97	0.93	0.55	ND	2.04
	28	0.95	0.36	0.30	ND	1.33
	Mean	0.96	0.65	0.43	-	1.68
52 w	29	1.07	0.77	ND	ND	1.61
	30	0.57	0.84	ND	ND	1.36
	Mean	0.82	0.81	-	-	1.49

^a Calculated from Total extractable (ethanol:water extractions 1 to 3) – (Amitrole + Degradates D,E and F)

ND: not detected

Table 8.1.1-9: TLC analysis (% AR) of soil extracts (aqueous ethanol extracts + soxhlet extracts) following application of ¹⁴C-amitrole – Group C (22°C, sterile)

Incubation time	Flask No	Amitrole	Degradate B	Degradate C	Unidentified calculated by RMS ^a
30 d	37	68.38	0.66	ND	3.74
	38	65.69	2.46	ND	6.39
	Mean	67.04	1.56	-	-
13 w	39	39.34	3.08	ND	7.32
	40	44.07	1.02	ND	4.70
	Mean	41.71	2.06	-	-
26 w	41	23.70	2.83	0.65	4.98
	42	34.05	2.08	0.97	2.18
	Mean	28.88	2.46	0.81	-
52 w	43	19.17	6.48	ND	2.83
	44	18.61	5.39	0.51	5.21
	Mean	18.89	5.94	0.26	-

^a Calculated from Total extractable (ethanol:water extractions 1 to 3 + soxhlet extraction) – (Amitrole + Degradates B and C)
ND: not detected

Table 8.1.1-10: HPLC analysis (% AR) of soil extracts (aqueous ethanol extracts) following application of ¹⁴C-amitrole – Group C (22°C, sterile)

Incubation time	Flask No	Amitrole	Degradate D	Unidentified calculated by RMS ^a
30 d	37	52.58	0.40	3.04
	38	49.76	0.50	4.20
	Mean	51.17	0.45	3.62
13 w	39	31.24	1.09	3.40
	40	31.05	1.20	3.39
	Mean	31.15	1.15	3.39
26 w	41	13.31	0.58	4.34
	42	16.31	1.21	1.99
	Mean	14.81	0.90	3.16
52 w	43	13.24	2.02	3.09
	44	12.70	1.49	5.78
	Mean	12.97	1.76	4.43

^a Calculated from Total extractable (ethanol:water extractions 1 to 3) – (Amitrole + Degradates D)
ND: not detected

Table 8.1.1-11: TLC analysis (% AR) of soil extracts (aqueous ethanol extracts + soxhlet extracts) following application of ¹⁴C-amitrole – Group D (7°C, viable)

Incubation time	Flask No	Amitrole	Degradate B	Unidentified calculated by RMS ^a
0 d	45	80.49	ND	8.17
8 h	46	81.44	ND	3.17
1 d	47	82.22	1.27	5.03
3 d	48	79.06	ND	3.71
5 d	49	76.87	ND	7.87
7 d	50	80.46	ND	2.25
10 d	51	83.93	ND	2.69
14 d	52	78.01	ND	5.79
21 d	53	72.27	1.60	4.23
30 d	54	66.18	3.60	3.56
8 w	55	53.58	ND	7.60
13 w	56	44.39	0.60	6.51
26 w	57	17.31	1.43	2.29
39 w	58	10.22	3.13	3.04
52 w	59	4.60	2.12	2.03

^a Calculated from Total extractable (ethanol:water extractions 1 to 3 + soxhlet extraction) – (Amitrole + Degradate B)
ND: not detected

Table 8.1.1-12: HPLC analysis (% AR) of soil extracts (aqueous ethanol extracts) following application of ¹⁴C-amitrole – Group D (7°C, viable)

Incubation time	Flask No	Amitrole	Degradate D	Unidentified calculated by RMS ^a
0 d	45	71.58	ND	7.69
8 h	46	75.59	ND	3.17
1 d	47	73.18	ND	4.25
3 d	48	74.03	ND	2.54
5 d	49	61.45	ND	6.90
7 d	50	69.40	ND	1.29
10 d	51	67.17	ND	2.02
14 d	52	67.08	ND	4.81
21 d	53	59.35	ND	3.67
30 d	54	56.82	ND	2.06
8 w	55	46.75	ND	6.06
13 w	56	31.15	0.77	5.56
26 w	57	8.49	ND	1.69
39 w	58	6.08	0.75	1.58
52 w	59	1.78	1.18	1.73

^a Calculated from Total extractable (ethanol:water extractions 1 to 3) – (Amitrole + Degradate D)
ND: not detected

Group A (22°C, viable)

Overall mean recoveries of applied radioactivity ranged from 90.22 to 99.97% AR for Group A. The recovery of radioactivity from the ethanolamine trap, as CO₂, increased throughout incubation reaching a maximum mean of 58.39% AR after 52 weeks. The evolution of the other non specific radiolabelled volatiles was negligible (<0.13%).

The level of non extractable radioactivity increased up to 41.18% AR (mean) after 26 weeks, and then decreased to 37.65% AR (mean) at the end of incubation. Extractable residues decreased from 88.46% at day 0 to 3.77% AR (means) at the end of incubation.

Degradate profiling using TLC indicated that amitrole and a minimum of 2 radiolabelled degradates were present. Amitrole was the main component present in the extracts but degraded rapidly (33.66% AR after 30 days). It decreased to 0.41% AR at the end of incubation. The minor compounds named degradates B and C were quantified. Degradate B reached a maximum of 4.06% AR after 30 days. Only one reference compound,

urazole, possessed similar chromatographic properties to degradate B. Degradate C did not exceed 0.28% AR (8 weeks).

Degradate profiling by HPLC indicated that amitrole and a minimum of 3 radiolabelled degradation products may be present in aqueous ethanol extracts. Amitrole degraded rapidly, decreasing to 27.15% AR (mean) after 30 days, and to 0.82% AR after 52 weeks. Three minor compounds, named degradates D, E and F were quantified. They reached a maximum of 1.13% AR after 14 days, 0.43% AR after 39 weeks and 0.10% AR after 26 weeks, respectively. The retention time of degradates D, E and F did not actually correspond with those of the available reference standards, but for degradate D, it was similar to that of aminoguanidine bicarbonate.

Group B (22°C, viable)

The use of NaOH to collect evolved radiolabelled volatiles confirmed that CO₂ was the sole radiolabelled component present in effluent gases from soil samples treated with ¹⁴C-amitrole.

Group C (22°C, sterile)

Total viable bacteria analysis showed that with 2 limited exceptions, sterile incubation conditions had been maintained during the incubation period. Overall mean recoveries of applied radioactivity ranged from 85.77 to 91.73% over the 52 weeks incubation period. The evolution of CO₂ was negligible (ca 1% after 52 weeks). No other radiolabelled volatiles were collected. The level of extractable residues reached a maximum of 55.48% AR after 52 weeks.

The degradation of amitrole was slower than under viable conditions. Degradate profiling using TLC indicated that amitrole represented 67.04% AR after 30 days, and 18.89% AR at the end of incubation. Degradates B and C were quantified at maximum levels of 5.94% AR after 52 weeks and 0.81% AR after 26 weeks, respectively. Degradate profiling using HPLC indicated that amitrole represented 51.17% AR after 30 days, and 12.97% AR at the end of incubation. Only degradate D was quantified at a maximum occurrence of 1.76% AR after 52 weeks.

Group D (7°C, viable)

Total recoveries of AR were in the range of 89.30 to 95.74% AR. The evolution of CO₂ increased steadily during incubation ultimately accounting for 44.17% AR by 52 weeks. The evolution of non specific radiolabelled volatiles was low, accounting for only 0.91% AR at the end of the incubation period. Unextractable residues reached 40.82% AR at the end of the study.

Degradate profiling using TLC indicated that amitrole represented 66.18% AR after 30 days, and 4.60% AR at the end of incubation. Degradate B was quantified at maximum levels of 3.60% AR after 30 days. Degradate profiling using HPLC indicated that amitrole represented 56.82% AR after 30 days, and 1.78% AR at the end of incubation. Only degradate D was quantified at a maximum occurrence of 1.18% AR after 52 weeks.

Group E (22°C, viable) and F (7°C, viable)

TVB analysis of samples from these groups demonstrated that soil samples at both study temperatures had remained viable throughout incubation.

□ Comments from RMS

The study is considered acceptable and more reliable than the previous studies summarized in the original DAR. It remains unclear why this study has never been submitted before.

The total recovery of radioactivity is sometimes slightly below 90% but it is considered acceptable. The study confirms the degradation pathway that had been proposed in the original DAR. Amitrole is rapidly degraded by microbial activity into CO₂. Mineralisation reached 44.5% AR after 13 weeks (91 days) and 58.39% AR after 52 weeks (365 days). Non extractable residues are also important, reaching 40.89% AR after 91 days and 37.65% AR after 365 days. No major metabolites were quantified. However, RMS noted that some unidentified radioactivity reaches levels above 10% on some occasions. RMS highlights that the HPLC reference standard of 1,2,4-triazole was used in the study, therefore it is not expected that this unknown radioactivity corresponds to 1,2,4-triazole. This should be confirmed by the applicant. **The applicant should also clarify whether the unidentified radioactivity is formed by several compounds or not and whether each compound exceeds 5% AR or not.** The applicant indicated at the end of December 2012 that this point was currently being checked.

B.8.1.1.1.2. Aerobic degradation of Amitrole – Additional data from literature

Dakhel, N., 2001 – Effets des paramètres pédo-climatiques sur les mécanismes responsables de la dissipation de l'amtrole dans les sols: adsorption, dégradation et stabilisation des résidus. PhD thesis.

Translation : Effects of pedoclimatic conditions on the mechanisms responsible for amitrole dissipation in soils: adsorption, degradation and stabilisation of residues.

□ Summary

Amitrole, or 3-amino-12,4-triazole, is a systemic foliar and non-selective herbicide used in vineyards, orchards and for weeding of non-agricultural lands. It is an aromatic amphoteric weak base that can form complexes with many metallic elements. Despite it is used since forty years in Europe, it appeared necessary to get more information about its fate in soils to assess the risks for ground water contamination.

This work is focused on the study of the major processes that are responsible for amitrole dissipation in soils: retention, degradation and stabilisation.

To study amitrole behaviour, 57 soils were sampled from 8 wine-growing regions in France. ^{14}C -amitrole was used for all experiments. Soil extractions were done with NH_4OH 0,54 M, and extracts were analysed with HPLC after their purification.

Amitrole retention in soils results from instantaneous processes followed by slower processes that are linked to its diffusion in the soil micro-porosity and are responsible for retention non-equilibrium. Amitrole interactions with soils are related to soil type. Retention is higher in acidic soils and is mainly due to ionic exchange. In neutral and calcareous soils, instantaneous retention is lower but retention increases more with time. Retention kinetics data are described with a simple empirical model $Q(t) = Q_0 + At^{0.5}$, where Q is the amount of amitrole retained with time, Q_0 is the amount of amitrole retained instantaneously, and A is an empirical parameter including all processes responsible for non-equilibrium. This model is used to describe amitrole retention kinetics in all soils sampled. An instantaneous sorption coefficient K_{do} was calculated from Q_0 values. Results analysis shows that:

- 1) amitrole retention varies greatly with soils,
- 2) retention is related to soil content in copper, that is abundant in vineyards soils and to pH,
- 3) retention increase with time is linked to soil content in organic and mineral colloids. Complexes formation between amitrole and copper and their effect on amitrole retention in soils were then studied. In aqueous solution, main complexes formed are neutral, with a structure $\text{Cu}(\text{A})_2$ and a stability constant $\log K$ ranging between 7 and 8. In the soil, complexation between amitrole and copper can occur in soil solution or at the soil solid surface. Amitrole retention in soil in both situations is studied as a function of pH. The most common case encountered in vineyard soils is formation of surface complexes between amitrole and copper that is already sorbed on soil particles. This leads to a great increase of amitrole retention in soils and a strong decrease of its liberation.

Amitrole mineralisation in soils varies greatly with soil type. However, it is generally rapid, as in 67% of soils, mineralisation half-life is shorter than 30 days. Mineralisation kinetics are described with a two exponential compartments model. No direct relationship between amitrole mineralisation and soil properties or amitrole retention is observed. Then, 8 soils were selected to investigate the mechanisms involved in amitrole degradation. Results showed that mineralisation is the most important pathway for amitrole degradation in soils. Mineralisation is biological, although it is not directly related to global microbial activity. This could be explained by the fact that amitrole can be used as a nitrogen source by microorganisms. A part of the residues that are not mineralised are stabilised by physical sequestration or formation of covalent binding with soil organic matter. These stabilised residues are slightly available for mineralisation.

Effects of temperature and moisture on amitrole degradation were also studied. This led to the conclusion that in most situations, amitrole is easily biodegraded in soils.

Dakhel, N., Barriuso, E., Charnay, M-P., Touratier, C., Ambrosi, D., 2001 – Amitrole degradation in vineyard soils in relation to pedo-climatic conditions. *Biol Fertil Soils* (2001) 33:490-494.

□ Summary

The fate of ^{14}C -amitrole herbicide was studied in eight soils having different capacities for amitrole mineralisation. Laboratory incubations were run combining different experimental conditions: temperature (4, 28

and 50°C), soil moisture (50, 100 and 150% of soil water holding capacity) and microbial activity (sterile and non-sterile conditions). During incubation, samples of the soils were periodically extracted with 0.5 M NH_4OH and extracts were analysed by HPLC. The lengths of time needed for 50% dissipation of amitrole (DT_{50}) in soils ranged from less than 1 day to more than 70 days. Amitrole mineralisation occurred only in non-sterile soils, showing that it is a biological process. Mineralisation was lower in soils with a coarse texture than in soils with a fine texture. Soil water content had little influence on the total amount of amitrole mineralised at the end of incubation. Temperature had a greater influence on mineralisation, although rates were still high at low and high temperatures. In non-sterile as in sterile soils, the major product detected in the extracts was amitrole. Additional non-identified radioactivity was occasionally extracted. However, it never represented more than 10% of initially applied amitrole. Non-extractable residues represented less than 15% of applied radioactivity in acidic soils and about 30% of applied radioactivity in alkaline and neutral soils. The amount of non-extractable radioactivity formed was enhanced in sterile when compared to non-sterile soils. Furthermore, in sterile soils, high temperature induced an increase of non-extractable residues, showing that amitrole is chemically quite reactive.

□ RMS comments

Both documents confirm the degradation pathway of amitrole that was described in the studies submitted in the DAR and in Hall (1994). They are considered as additional information.

RMS noted that the DT_{50} mentioned in these documents can reach values significantly longer (1 to 70 days) than the ones reported in the original DAR (< 5 days). Therefore, the applicant was asked to include these values in the risk assessment, in the case they were obtained under representative conditions and considered relevant. The applicant did not discuss the relevance of the values.

RMS checked the data available in the thesis. Among the 57 soils initially tested, further experiments to determine the DT_{50} of amitrole were conducted on 8 soils. Among these 8 soils, results from 3 soils only may be used to derive DT_{50} values (for the 5 other soils, only 2 or 3 data points are reported in the thesis). However, RMS noted that these 3 soils belong to the 6 soils among 57 which have the lowest mineralization of amitrole. In addition, the experiments were performed at 28°C and pH 3, which is quite dry compared to usual standard conditions. No information on microbial activity is reported. No measurement of amitrole at time 0 is available. RMS considers that results from the thesis bring interesting additional information, but it would be difficult to use these DT_{50} within the framework of risk assessment. Consequently, they will not be included.

B.8.1.1.2. Supplementary studies

B.8.1.1.2.1. Anaerobic degradation

No additional study was submitted, please refer to the DAR for details. A summary of fate and behaviour in soil is provided in B.8.1.3.

B.8.1.1.2.2. Photodegradation on soil

No additional study was submitted, please refer to the DAR for details. A summary of fate and behaviour in soil is provided in B.8.1.3.

B.8.1.2. Rate of degradation (annex IIA 7.1.1.2)

B.8.1.2.1. Laboratory studies (annex IIA 7.1.1.2.1)

B.8.1.2.1.1. Determination of degradation kinetic parameters of amitrole in soils under aerobic conditions at 20° C

The applicant was asked to provide a new kinetic assessment of data provided in the original DAR according to FOCUS recommendations. In addition, since it was seen in the studies of Dakhel (2001) presented under Point B.8.1.1.1 that significantly longer DT_{50} compared to the ones reported in the original DAR were mentioned, the applicant was asked to include them in the risk assessment in the case they were obtained under representative conditions and considered relevant.

The new kinetic assessment is presented below.

Comoretto, L., 2012a – Estimating persistence and degradation kinetics from environmental fate studies on Amitrol. Document No: NUFkinetic31082012.

- ☐ **Guidelines:** FOCUS 2006
- ☐ **GLP:** Not relevant
- ☐ **Deviations:** Yes, see comments
- ☐ **Acceptability:** Partly acceptable
- ☐ **Method**

Data from laboratory studies presented in the original DAR, from the additional study of Hall (1994) and from a part of the thesis of Dakhel (2001) were re-assessed to derive new DT50 according to FOCUS Kinetic guidance document. The excel spreadsheet FOCUS_DEGKIN_v2 was used. SFO kinetic was tested for each soil. When considered necessary, FOMC kinetic was also tested.

The following laboratory studies were taken into account: Hall, 1994 (summarised under B.8.1.1.1), Hawkins *et al.*, 1982a (summarised in the DAR; 2 soils), Jarczyk, 1988a-c (summarised in the DAR, 3 soils). From Dakhel (2001), data from 3 soils among 8 were selected (data are reported under B.8.1.1.1). Raw data from the studies were taken into account without any change, except for Jarczyk study: the data were reported in mg/kg and were transformed to % by the applicant.

Raw data from the studies summarised in the original DAR are reported below. Data from other studies are available under point B.8.1.1.1.

Table 8.1.2-1: Percentage recovery of radioactivity – Hawkins *et al.*, 1982a

Time after application	Sample	3,5 ¹⁴ C		3,5 ¹⁴ C	5 ¹⁴ C
		Soil A		Soil B	Soil A
		Anaerobic	Aerobic	Aerobic	Aerobic
		% Radioactivity extracts	% Radioactivity extracts	% Radioactivity extracts	% Radioactivity extracts
0 (1)	1	22.5	85.7		(34.8)
0 (1)	2	19.6	88.1		(38.5)
3	1				12.1
3	2				17.2
7	1	24.7	2.7	10.4	12.8
7	2	24.8	3.0	11.4	2.2
14	1	22.3	1.5	4.7	6.4
14	2	21.5	2.1	4.7	1.1
28	1	20.4	0.92	0.7	0.68
28	2	22.0	0.97	1.6	0.88
56	1	19.7	0.98		
56	2	17.2	1.3		
112	1	19.2	0.42		
112	2	18.3	0.47		
224	1	15.1	0.44		
224	2	11.6	0.3		
364	1	9.2	0.25		
364	2	9.7	0.28		

Table 8.1.2-2: Percentage recovery of radioactivity – Jarczyk, 1988a-b

Days after start of study	mg/kg in soil 1	mg/kg in soil 2
0	0.20	0.20
1	0.17	0.14
2	0.10	0.13
7	0.04	0.04
14	0.05	0.04
17	0.02	n.n.

Table 8.1.2-3: Percentage recovery of radioactivity – Jarczyk, 1988c

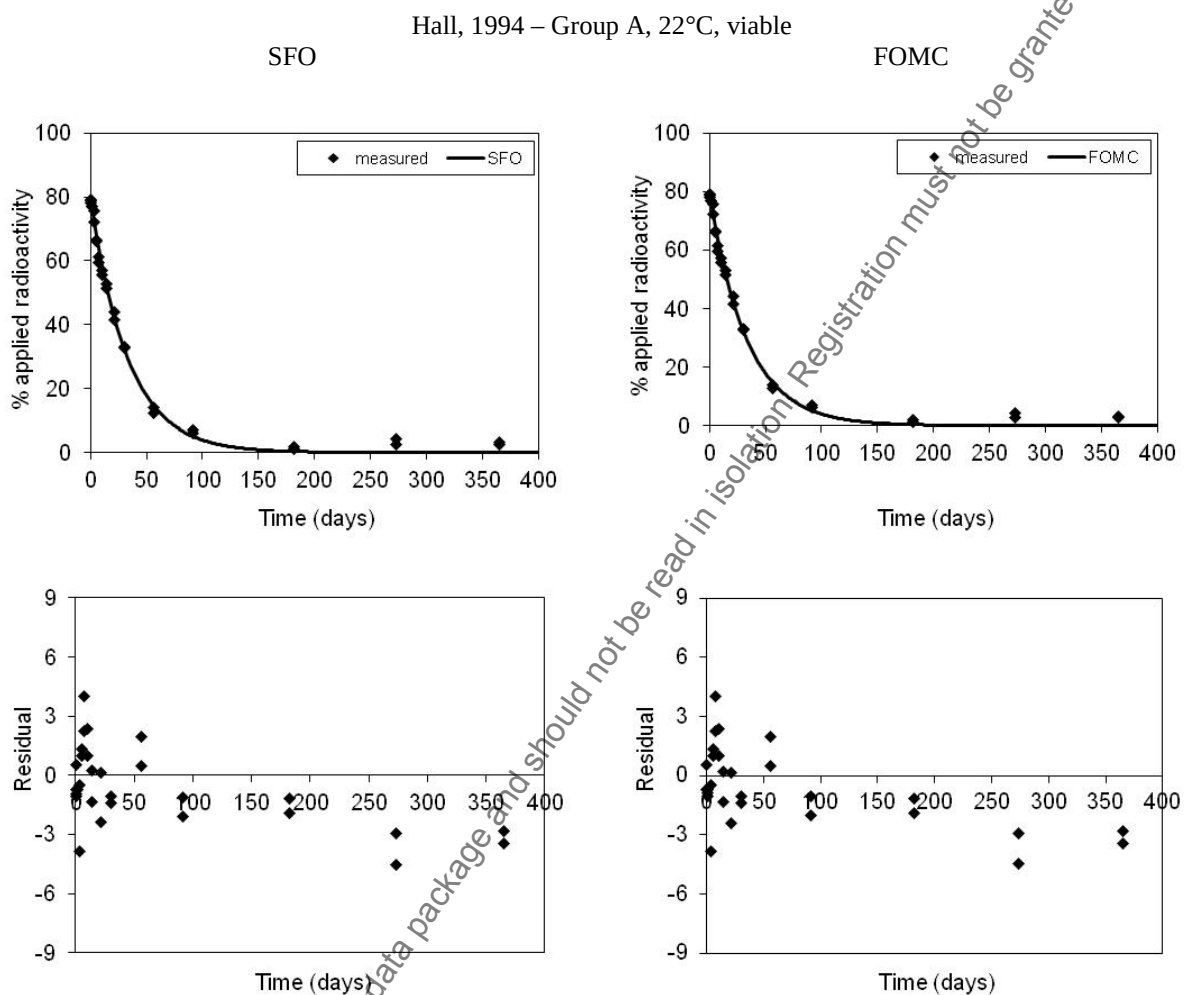
Days after start of study	mg/kg in soil 1
0	0.20
1	0.20
2	0.16
7	0.10
14	0.05
17	n.n.

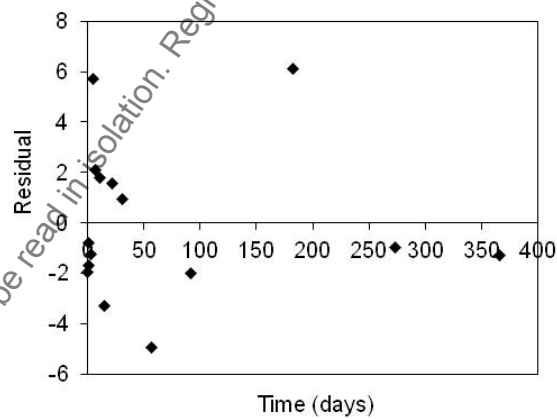
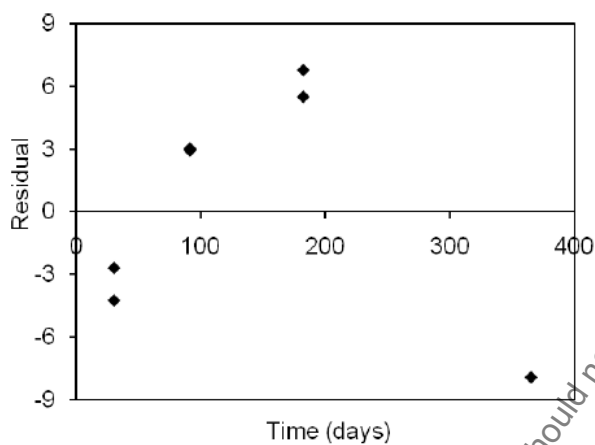
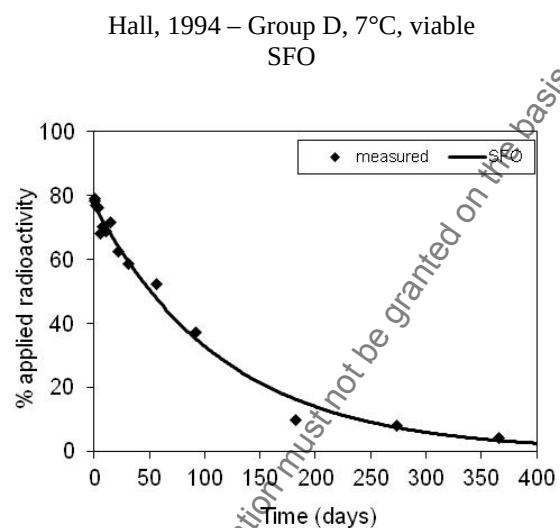
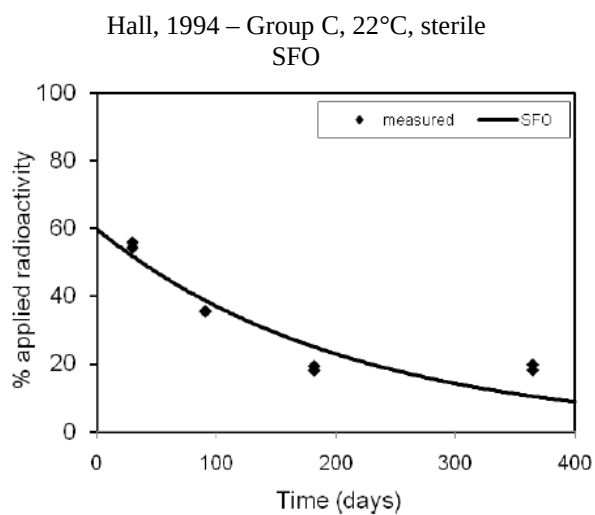
Normalised DT50 are also reported in the study. For temperature, an activation energy of 65400 J/mol was used. For moisture, it is reported that the ratio M/Mref depends on the nature of the soil. Values of 0.86 for sandy loam soil, 1 for sandy soil, 0.82 for clay loam soil and 0.79 for silt soil were used. It is reported that these values are

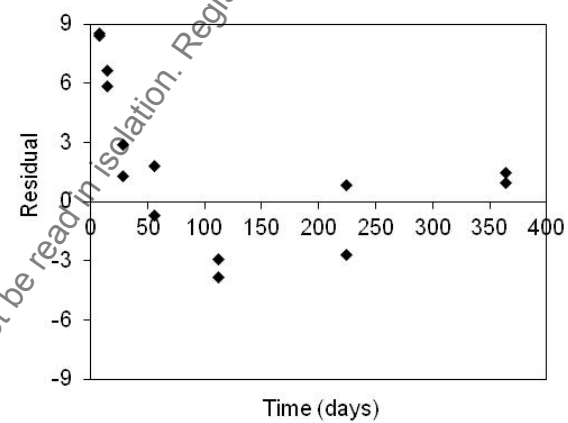
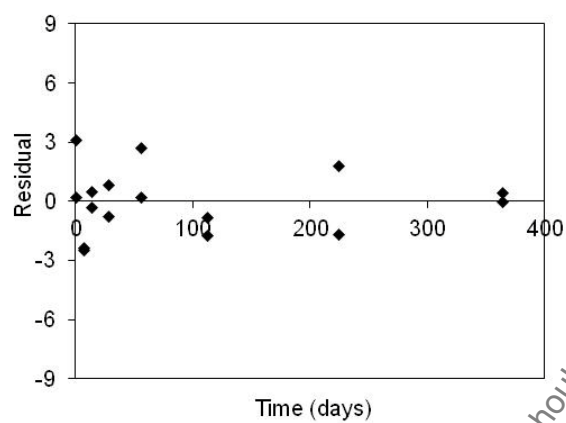
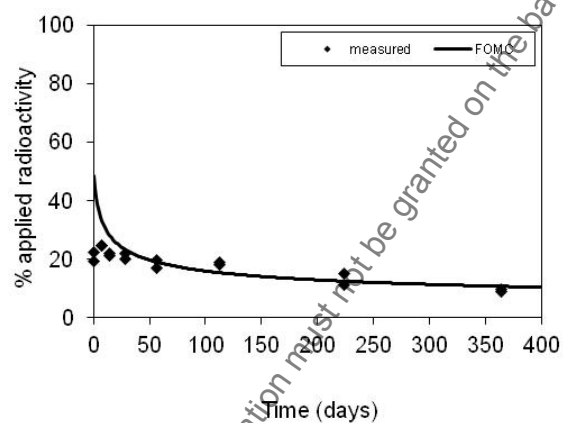
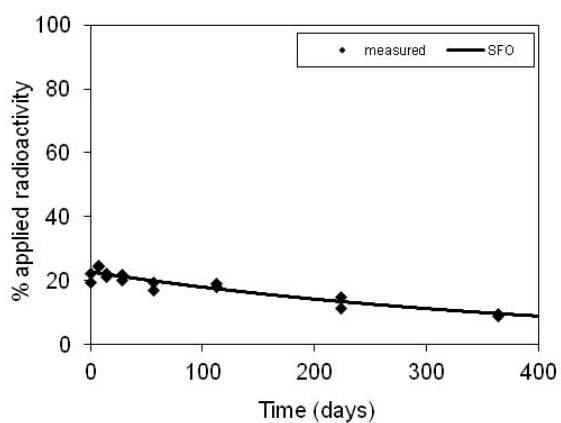
default values provided in the FOCUS groundwater guidance document. The moisture exponent used is not reported.

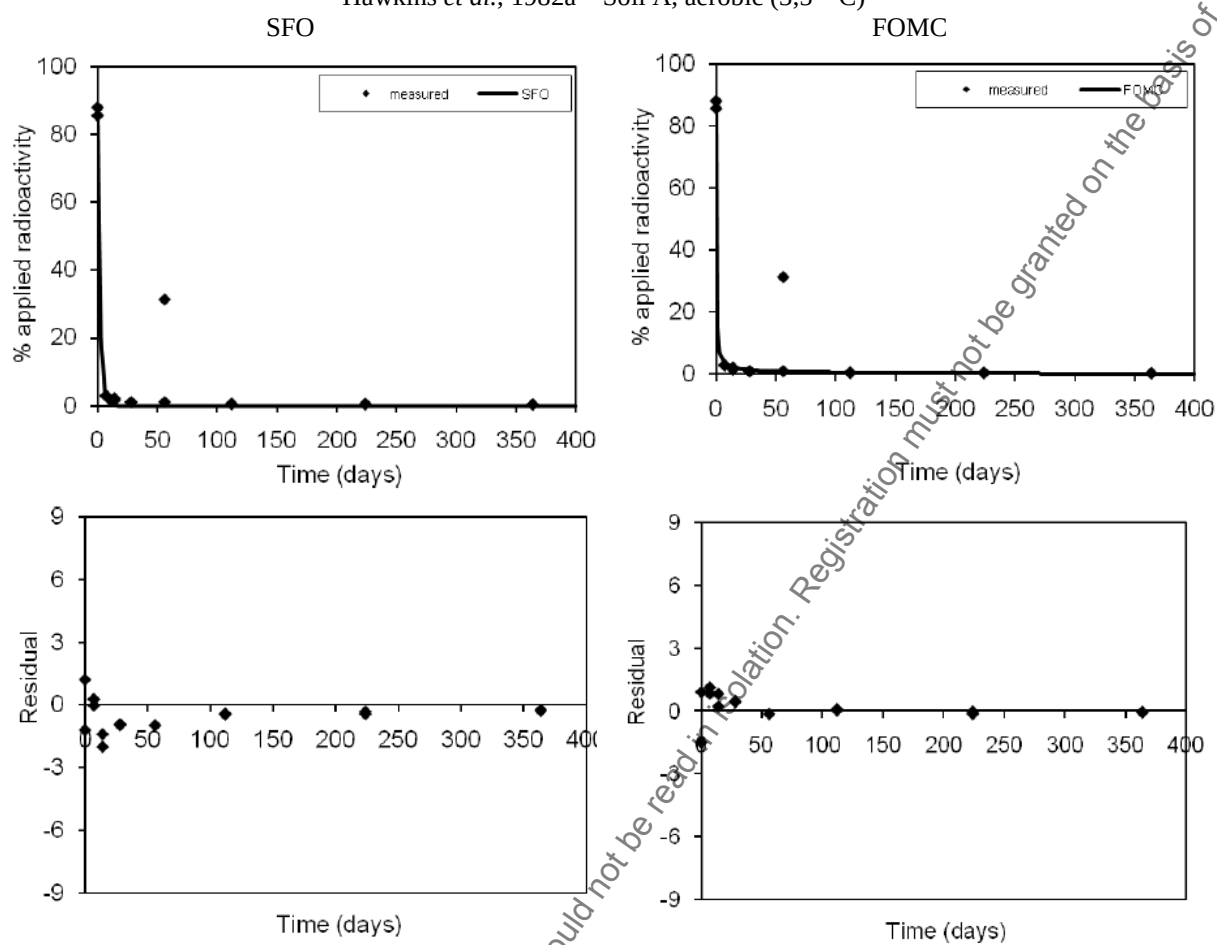
□ Findings

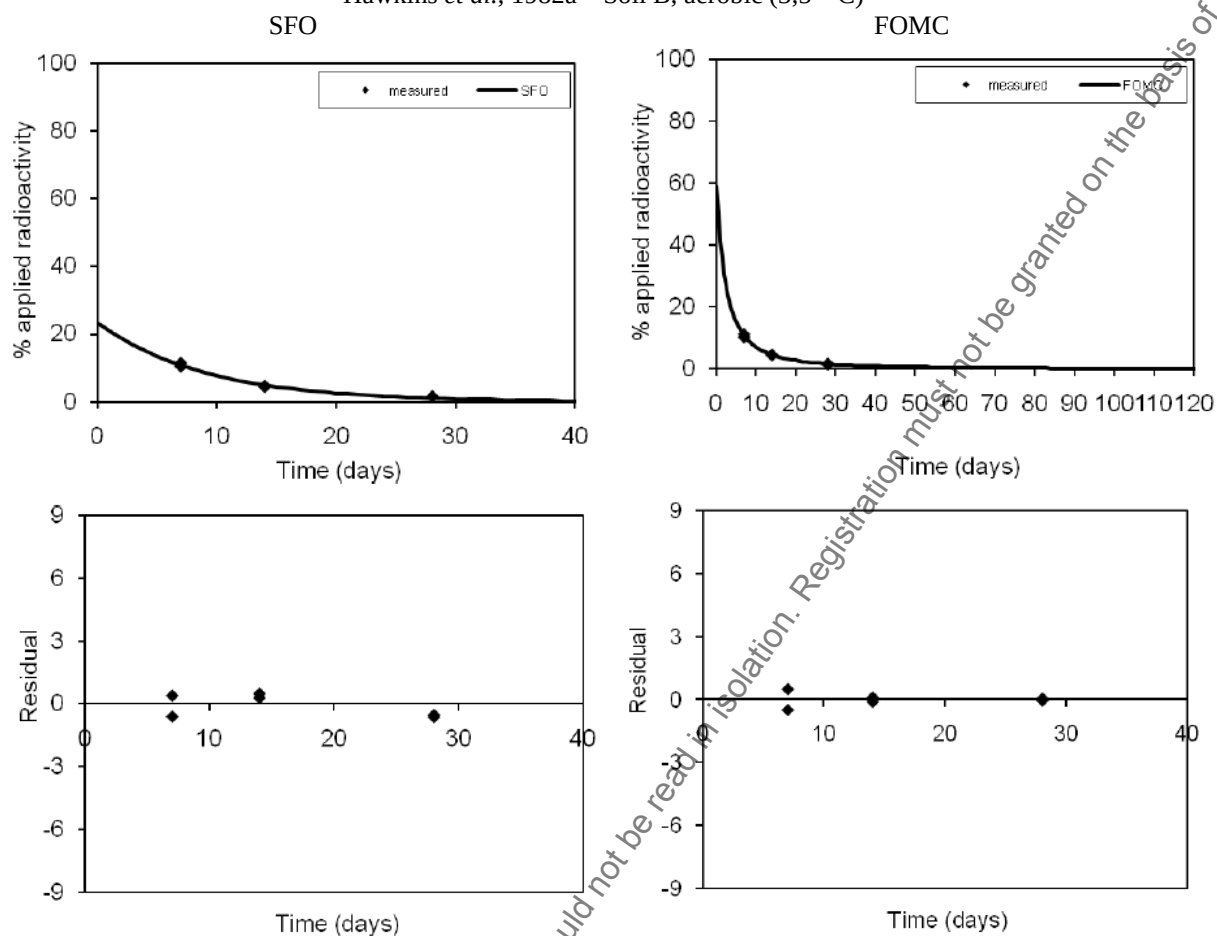
Visual fits and residual plots obtained for each soil with SFO and FOMC models are presented below.

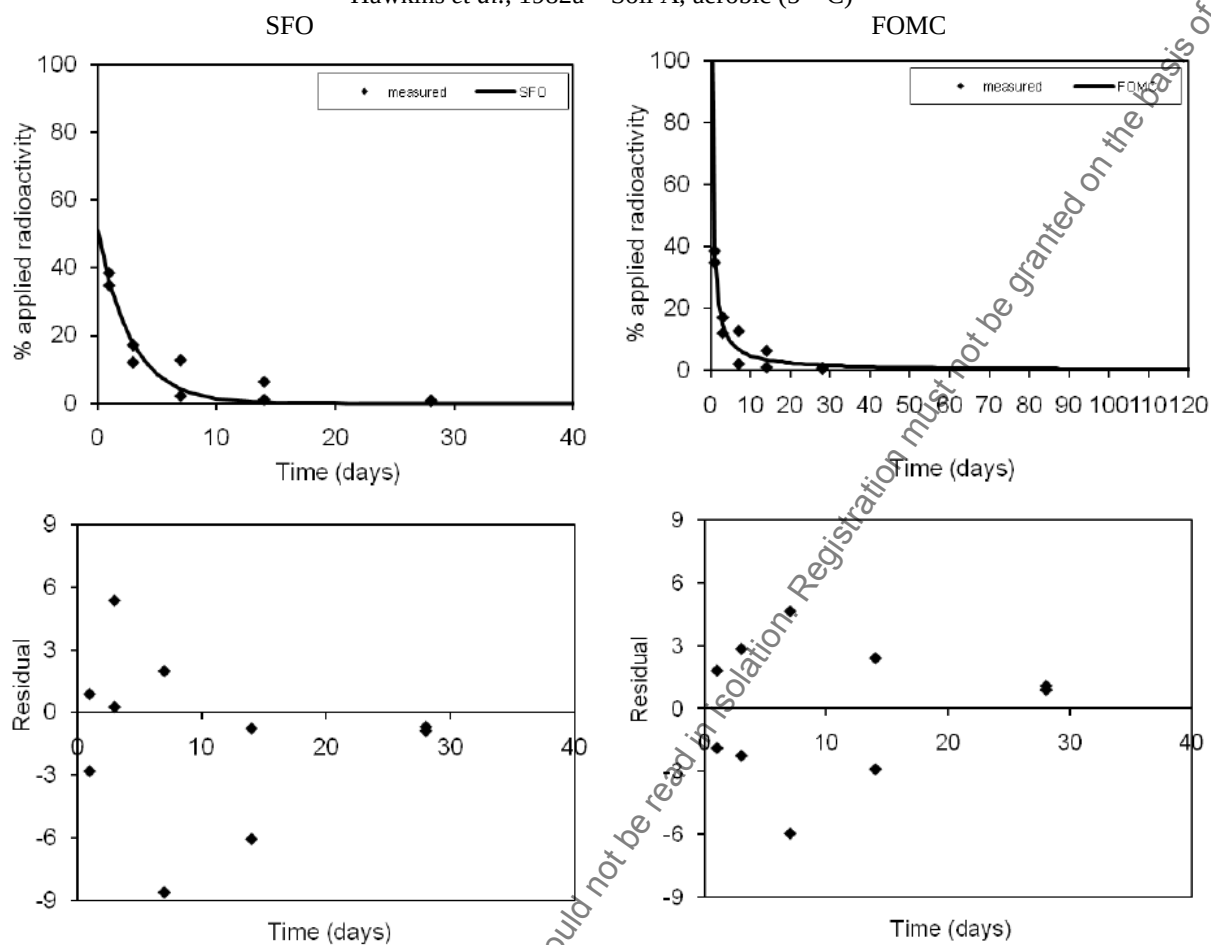




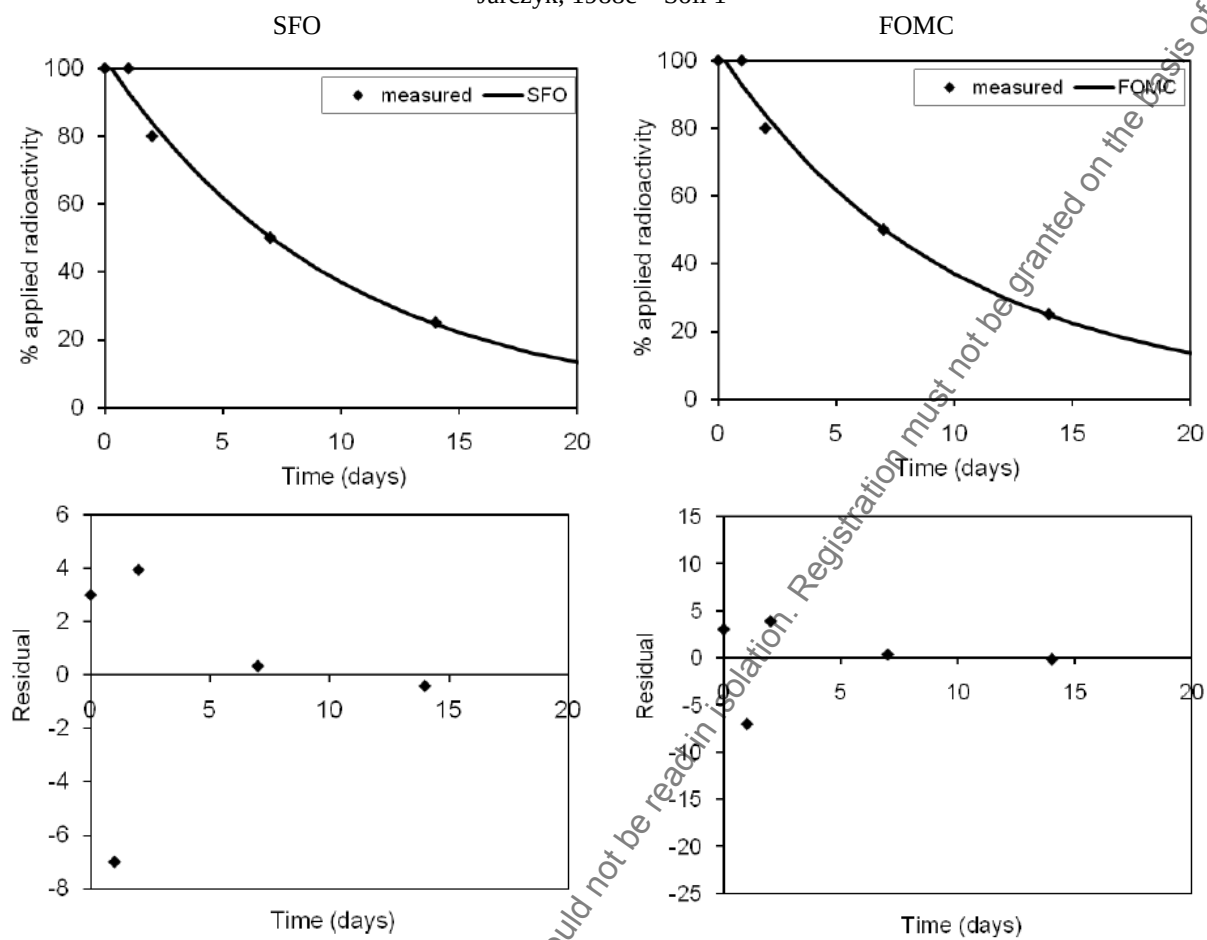
Hawkins *et al.*, 1982a – Soil A, **anaerobic** (3,5-¹⁴C)
SFO FOMC

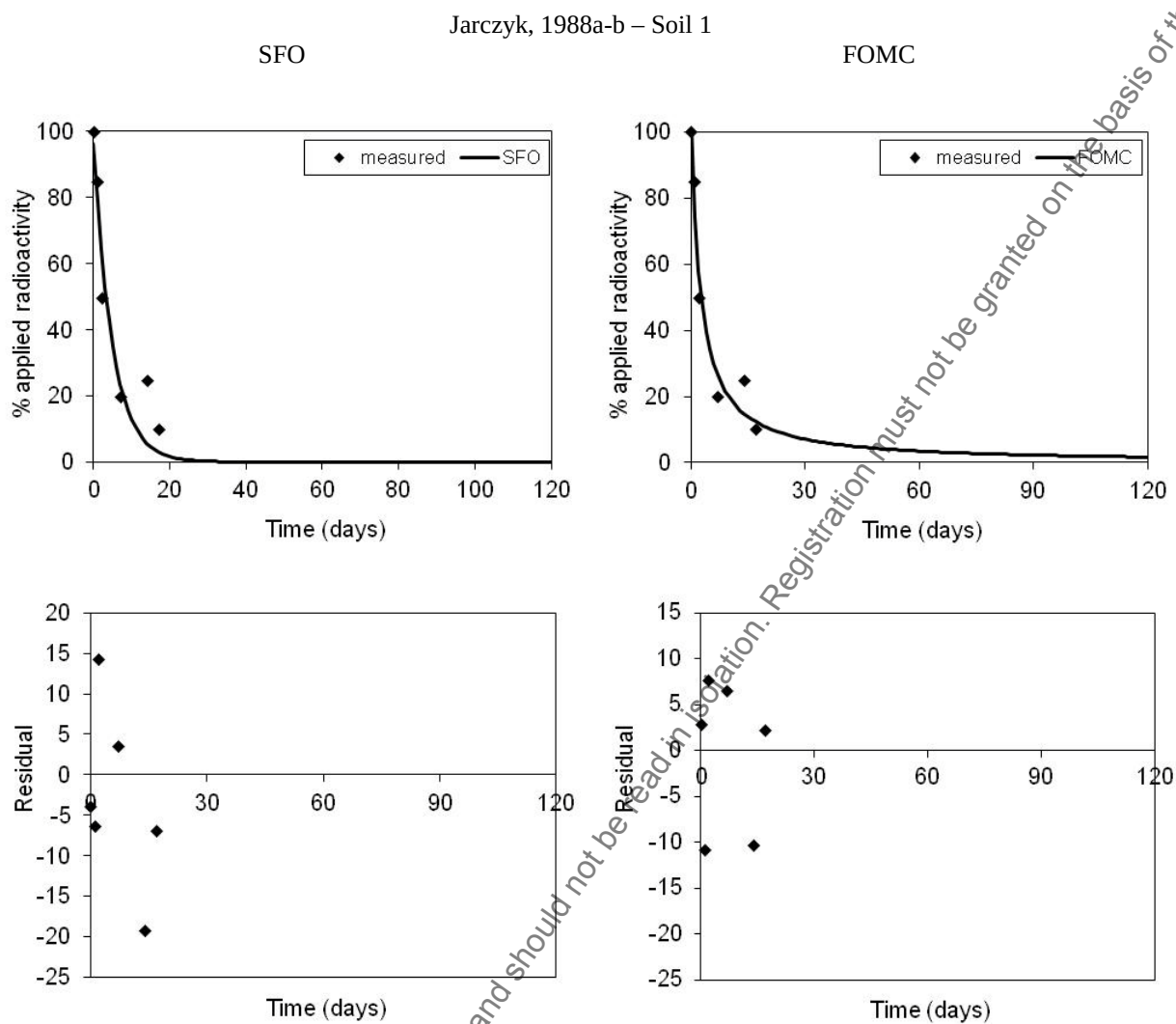
Hawkins *et al.*, 1982a – Soil A, aerobic (3,5-¹⁴C)

Hawkins *et al.*, 1982a – Soil B, aerobic (3,5-¹⁴C)

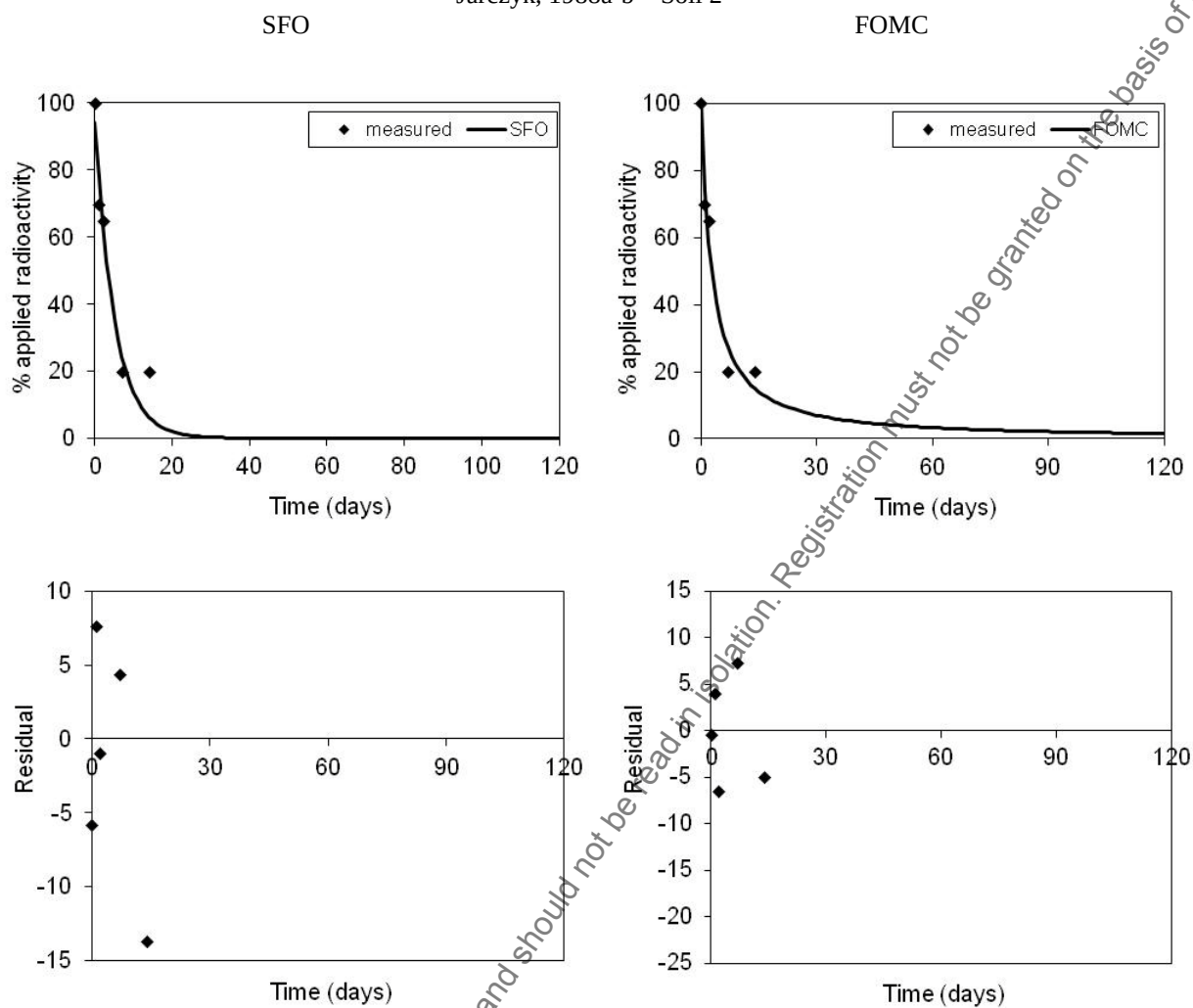
Hawkins *et al.*, 1982a – Soil A, aerobic ($5\text{-}^{14}\text{C}$)

Jarczyk, 1988c – Soil 1

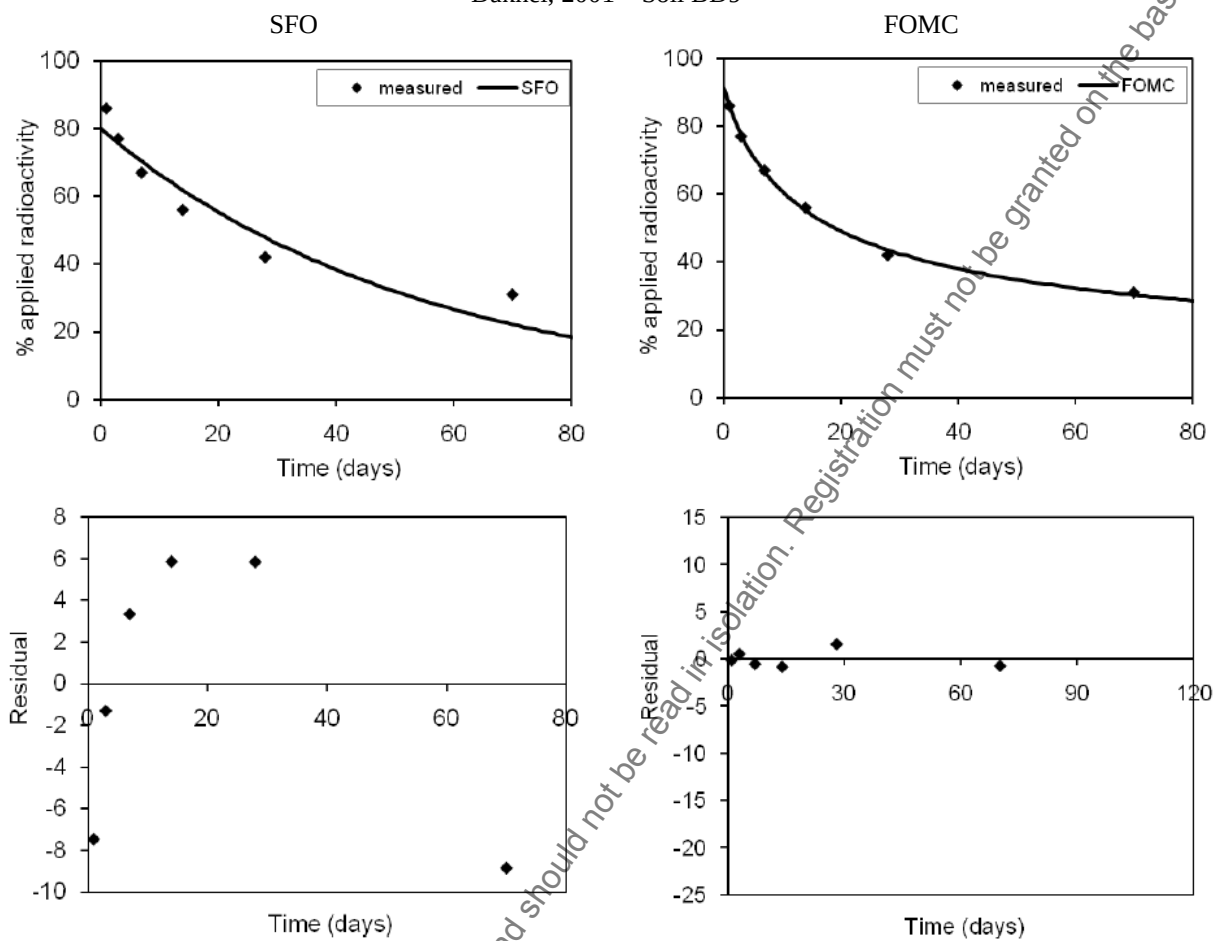




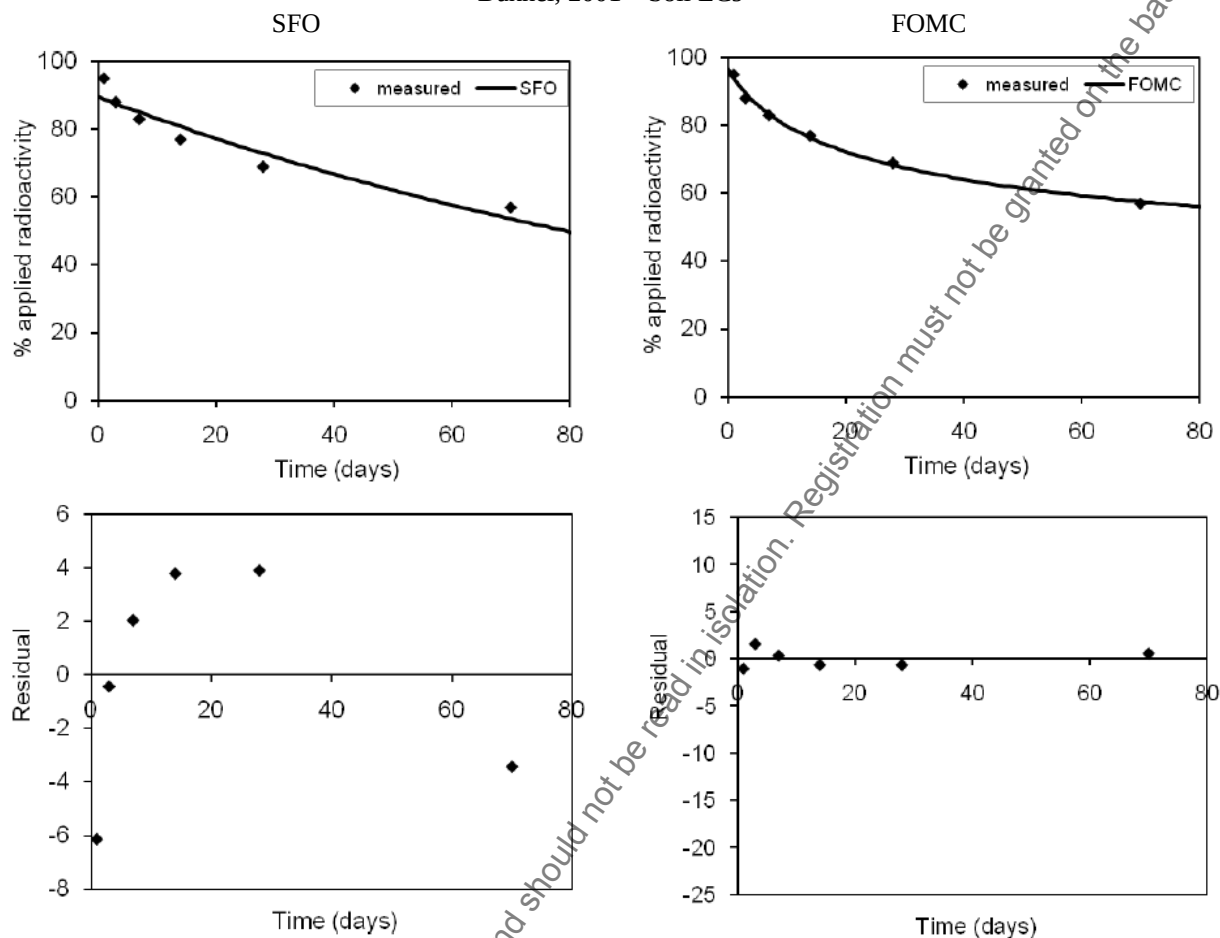
Jarczyk, 1988a-b – Soil 2

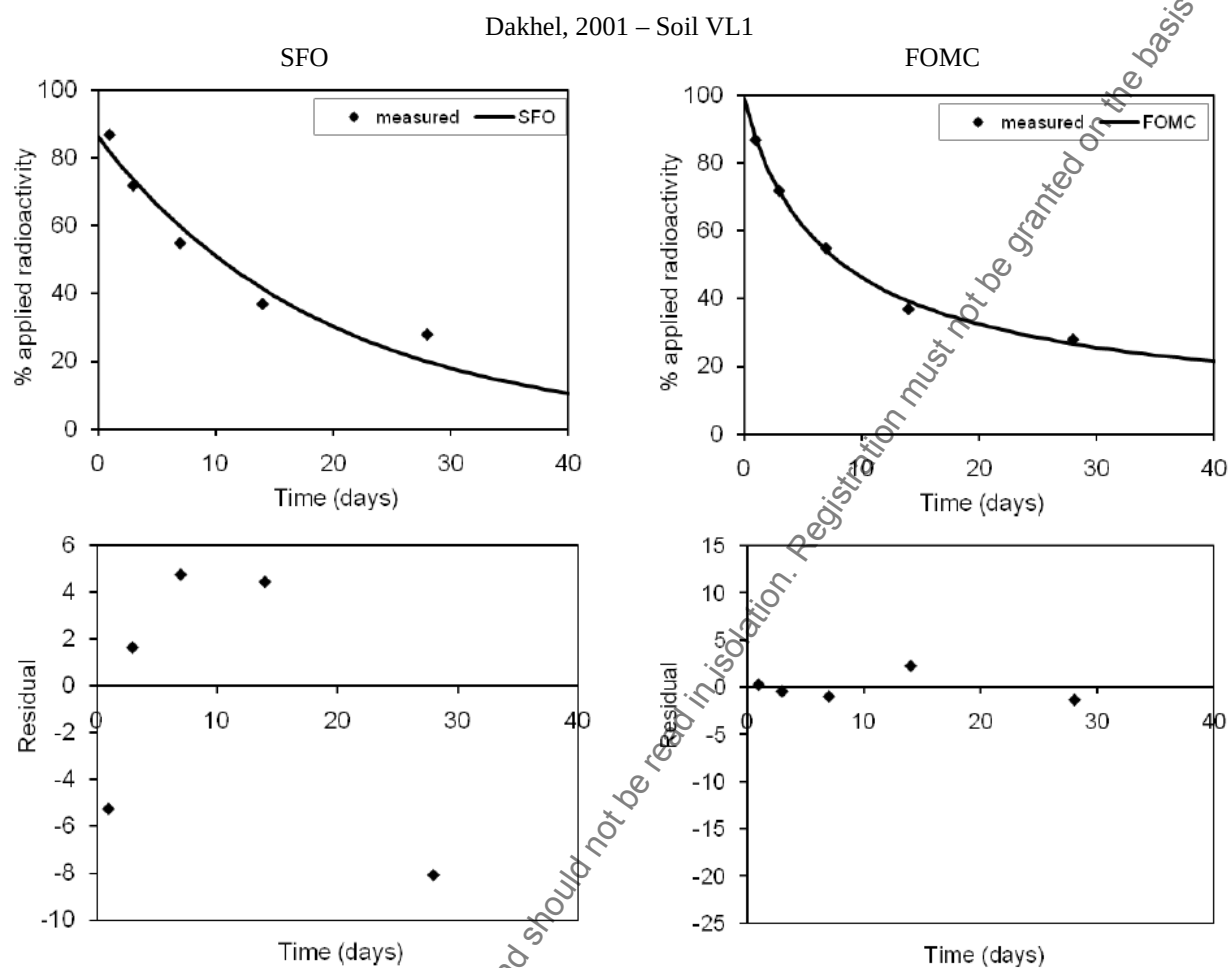


Dakhel, 2001 – Soil BD9



Dakhel, 2001 – Soil LC9



**Figure 8.1.2-1: Visual fits and residual plots**

Kinetic parameters and χ^2 are reported in the table below.

Table 8.1.2-4: Kinetic parameters

Soil	Model	Kinetic parameters	χ^2	DT50 (days)	DT90 (days)
Hall, 1994 Group A, 22°C, viable	SFO	k=0.030	3.5	23.2	76.9
	FOMC	$\alpha=211.482$ $\beta=7046.8$	3.6	23.1	77.1
Hall, 1994 Group C, 22°C, sterile	SFO	k=0.005	14.7	144.9	481.4
Hall, 1994 Group D, 7°C, viable	SFO	k=0.009	4.4	81.1	269.3
Hawkins <i>et al.</i> , 1982a Soil A, <u>anaerobic</u> 3,5 ^{14}C	SFO	k=0.002	5.3	295.6	982.1
Hawkins <i>et al.</i> , 1982a Soil A, aerobic 3,5 ^{14}C	SFO	k=0.482	33.4	1.4	4.8
	FOMC	$\alpha=0.731$ $\beta=0.1$	33.6	0.2	2.2
Hawkins <i>et al.</i> , 1982a Soil B, aerobic 3,5 ^{14}C	SFO	k=0.110	6.3	6.3	20.8
	FOMC	$\alpha=1.827$ $\beta=4.6$	Not reported	2.1	11.6
Hawkins <i>et al.</i> , 1982a Soil A, aerobic 5 ^{14}C	SFO	k=0.357	16.0	1.9	6.4
	FOMC	$\alpha=1.001$ $\beta=0.4$	4.0	0.4	3.4
Jarczyk, 1982 Soil 1	SFO	k=0.201	17.6	3.4	11.4
	FOMC	$\alpha=1.104$ $\beta=2.908$	13.6	2.5	20.5
Jarczyk, 1982 Soil 2	SFO	k=0.193	11.3	3.6	11.9
	FOMC	$\alpha=1.176$ $\beta=3.488$	8.7	2.8	21.2
Jarczyk, 1982 Soil 3	SFO	k=0.102	4.3	6.8	22.5
	FOMC	$\alpha=52.618$ $\beta=510.885$	5.0	6.8	22.9
Dakhel, 2001 Soil VL1	SFO	k=0.052	7.5	13.3	44.1
	FOMC	$\alpha=0.702$ $\beta=5.129$	2.1	8.6	131.2
Dakhel, 2001 Soil LC9	SFO	k=0.007	3.8	94.5	314.0
	FOMC	$\alpha=0.219$ $\beta=7.208$	1.0	164.6	270778.4
Dakhel, 2001 Soil BD9	SFO	k=0.018	8.0	37.8	125.5
	FOMC	$\alpha=0.464$ $\beta=7.144$	1.2	24.7	1018.8

Normalised DT50 values were calculated for SFO kinetic only. The following summary of DT50 is given in the report.

Table 8.1.2-5: Summary of laboratory soil DT50

Type of soils	SFO			FOMC		References
	DT50	Residual mean of squares	Normalised DT50	DT50	Residual mean of squares	
Groupe A 22°C Viable, dark	23.2	122	29	23.1	52	B.E. Hall, 1994
Groupe C 22°C Sterile, dark	144.9 ¹	273	n.a.	n.a.	n.a.	
Groupe D 7°C Viable, dark	81.1	132	66	73		
² Soil A, Anaerobic	n.a.		n.a.	28	25	Hawkins <i>et al.</i> , 1982a
² Soil A, aerobic	1.4	992	n.a.	n.a.		
² Soil B, anaerobic	6.3	1.5	n.a.	2.1	0	
² Soil A, anaerobic	1.9	154	n.a.	0.4	1.5	
² Soil A, aerobic	17.1	54	n.a.	46.7	6	
BD9 à 28°C	37.8	216	47	24.7	4	Dakhel, 2001
LC9 à 28 °C	94.5	83	114	164.7	5	
VL1 à 28°C	13.3	137	17	8.6	8	
Soil 1, 22°C	6.8	74	8	6.8	74	Jarczyk, 1982
Soil 2 22°C	3.4	690	4	2.5	337	
Soil 1 22°C	3.6	300	4	2.8	138	
Worst case	94.5		114	164.7		
Median			23			
Geomean			20			

¹: Not taken into account for the calculation of the mean DT50²: No temperature available**❑ Comments from RMS**

The applicant did not provide any clear conclusion on the acceptability of the kinetic fitting in the study. For each soil, it is not specified whether SFO or FOMC is selected. No statistical parameters except the χ^2 were provided.

In addition, when checking the raw data from the original studies, it appeared that for the studies of Hawkins *et al.* (1982a) and Hall (1994), the applicant used the total extractable radioactivity to derive DT50 values instead of the radioactivity corresponding to extractable amitrole. Therefore, the calculations proposed for these studies are not acceptable.

Data from Dakhel (2001) were included in the kinetic analysis without arguing on their relevance in the context of risk assessment. As explained by RMS under B.8.1.1.1.2, it is considered that these values should not be included in the risk assessment.

For data from Jarczyk (1988a-c), the kinetic analysis performed by the applicant was checked and is considered acceptable. However it was completed by RMS since t-test or confidence intervals were not reported in the study.

Finally, the way of normalising for moisture content is not very transparent and could not be reproduced by RMS.

Therefore, RMS performed a new kinetic assessment of the data from Hall (1994) and Hawkins *et al.* (1982a) and completed the analysis for Jarczyk (1988 a-c). Normalisation for temperature and moisture was redone for all soils. Details are given below.

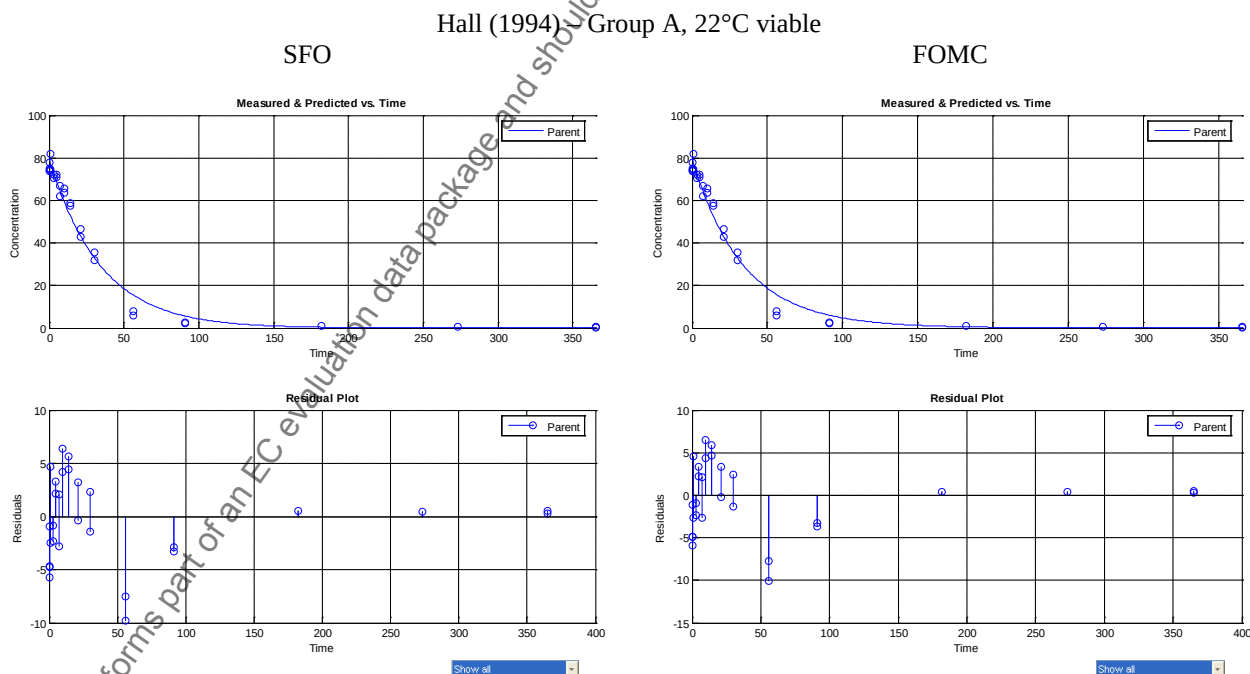
When checking the data from Hawkins *et al.* (1982a), it appeared that no sufficient data are available to derive reliable kinetic DT50. The data are reported below for information. It can be seen that depending on the systems tested, only 1, 3 or 4 data points would be available for fitting. It is not considered sufficient.

Table 8.1.2-6: Percentages of Amitrole found in the study of Hawkins *et al.* (1982a)

Soil type	Label	Application rate (mg/kg)	Time after application (days)	Amitrole (% AR)
A	3,5-14C	1	0	79.7
A	5-14C	1	1	25.1
			3	8.9
			7	5.2
			7	8.6
B	3,5-14C	1	14	3.3
			28	1.1
			28	1.1
A	5-14C	10	3	19.8
			7	21.7
			14	1.7
			28	2.1

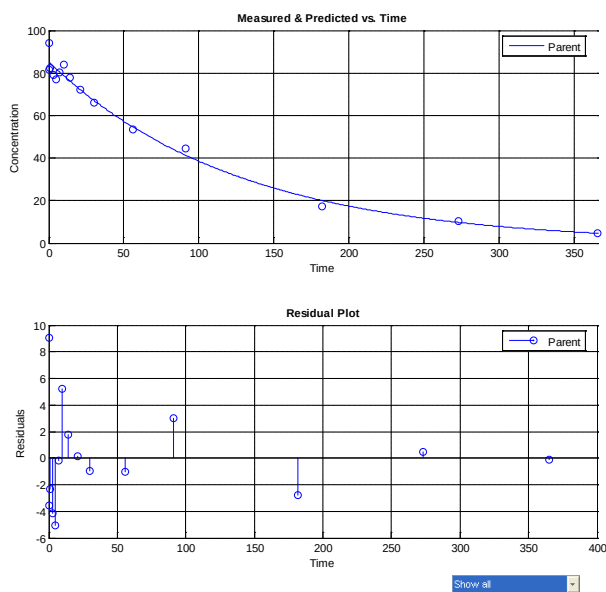
Therefore, the kinetic assessment was only performed for Hall (1994) and Jarczyk (1988 a-c). As recommended in the FOCUS Kinetic guidance document, when bound residues or metabolites were present at day 0, their amount were added to the parent amount. The kinetic analysis was performed using the software KinGUI 1.0. SFO and FOMC models were tested for each soil. When FOMC seemed better than SFO, DFOP model was tested. The best kinetic was selected based on visual fits, residual plots, χ^2 value, t-test and confidence interval.

Visual fits and residual plots are presented below.

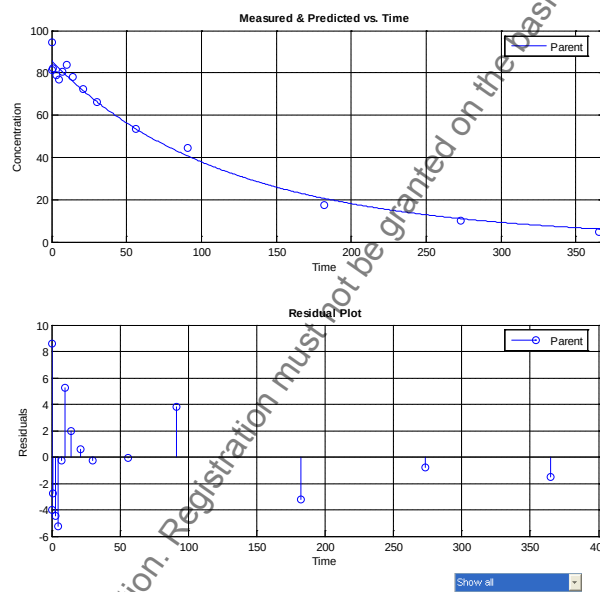


Hall (1994) – Group A, 7°C viable

SFO

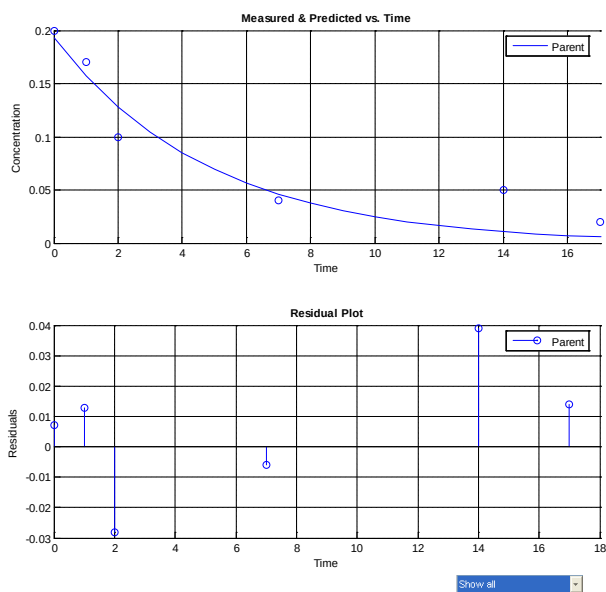


FOMC

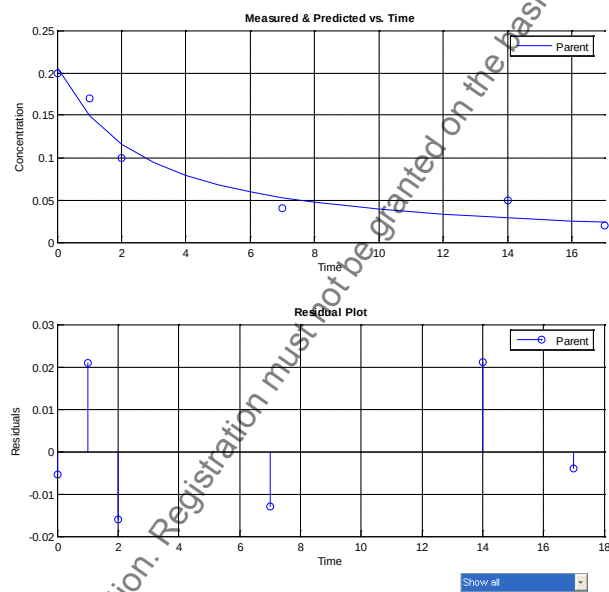


Jarczyk (1988a,b) – Soil 1

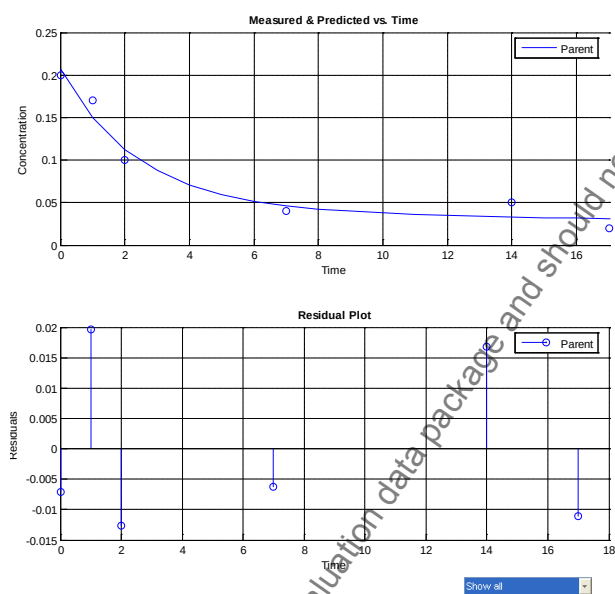
SFO



FOMC

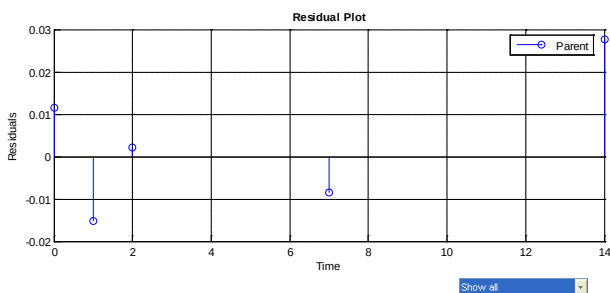
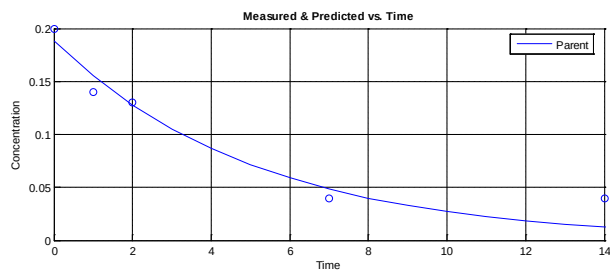


DFOP

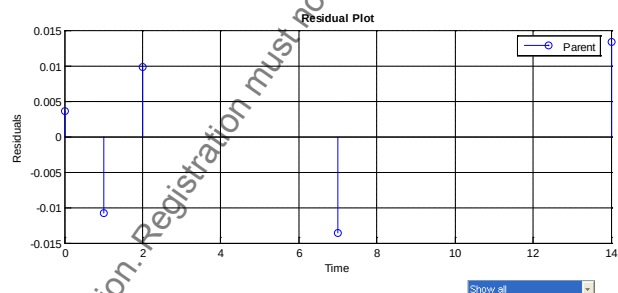
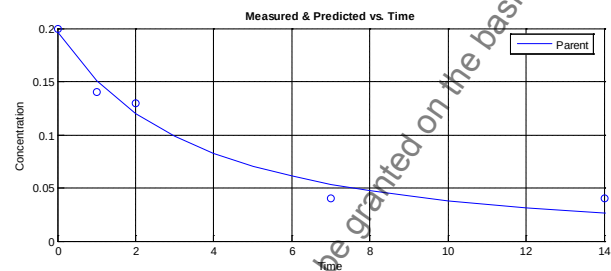


Jarczyk (1988a,b) – Soil 2

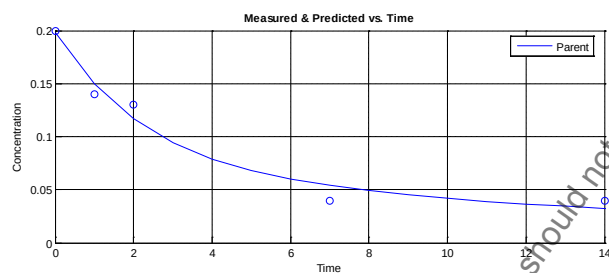
SFO



FOMC



DFOP



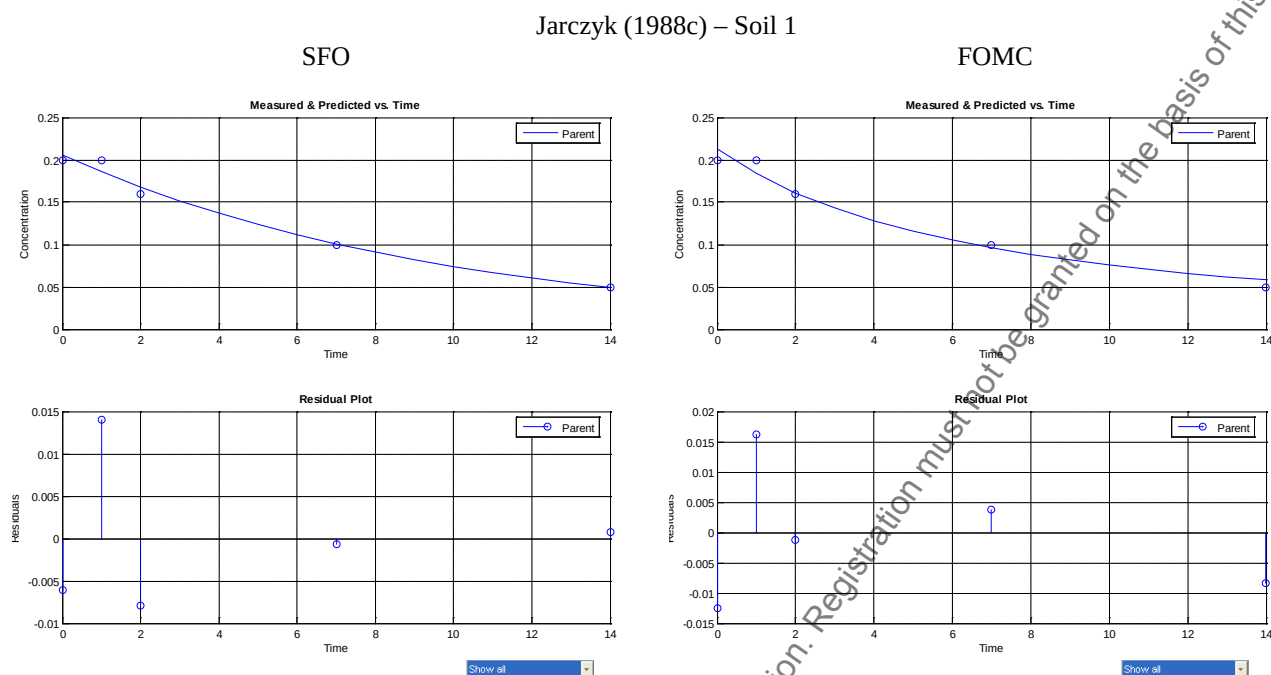


Figure 8.1.2-2: Visual fits and residual plots for Amitrole degradation

Kinetic parameters and statistical results are reported in the following table.

Table 8.1.2-7: Kinetic parameters and statistical results

Study	Soil	Model	Kinetic parameters	χ^2	t-test	0 included in confidence interval Y/N	DT50 (days)	DT90 (days)
Hall (1994)	Group A, 22°C	SFO	k=0.0291	6.7	9.7e-17	N	23.8	79.1
		FOMC	$\alpha=26.778$ $\beta=900.345$	7.2	-	α : Y β : Y	23.6	80.8
	Group D, 7°C	SFO	k=0.0079	4.8	2.4e-9	N	87.2	289.7
		FOMC	$\alpha=7.697$ $\beta=892.964$	5.1	-	α : Y β : Y	84.1	311.4
Jarczyk (1988a,b)	Soil 1	SFO	k=0.2048	17.6	0.018	N	3.4	11.2
		FOMC	$\alpha=1.1525$ $\beta=3.1213$	13.6	-	α : Y β : Y	2.6	19.9
		DFOP	$k_1=0.4162$ $k_2=0.0187$ $g=0.7945$	13.6	k_1 : 0.1645 k_2 : 0.4543	k_1 : Y k_2 : Y g : Y	2.3	38.6
	Soil 2	SFO	k=0.1942	11.3	0.0148	N	3.6	11.9
		FOMC	$\alpha=1.5754$ $\beta=5.4745$	9.0	-	α : Y β : Y	3.0	18.1
		DFOP	$k_1=0.4362$ $k_2=0.0576$ $g=0.6377$	10.6	k_1 : 0.2998 k_2 : 0.4077	k_1 : Y k_2 : Y g : Y	2.8	22.3
Jarczyk (1988c)	Soil 1	SFO	k=0.1023	4.3	0.0014	N	6.8	22.5
		FOMC	$\alpha=1.3755$ $\beta=8.9939$	6.5	-	α : Y β : Y	5.9	39.0

For group A and D from Hall (1994) and for soil 1 from Jarczyk (1988c), SFO gave good visual fits, good χ^2 value, and the kinetic parameters are significant. FOMC does not improve the fits. Therefore, SFO was selected.

For soils 1 and 2 from Jarczyk (1988 a,b), SFO gives acceptable fits but the last point is slightly underestimated. However, the kinetic parameters are significant. Only the χ^2 value for soil 1 slightly exceed 15%. Since visual fit with FOMC is better for both soils, DFOP model was also tested. It appeared that the degradation behavior is better described with biphasic models, however the kinetic parameters are not significant (t-test failed or 0 was included in the confidence interval). As a consequence, since SFO was acceptable enough, it was selected for both soils.

Acceptable data were then normalised for temperature and moisture content. For temperature, an activation energy of 65.4 kJ/mol was used. For moisture, a Walker exponent of 0.7 was used. Details of the normalisation are reported below. For Hall (1994), two DT50 values are available. However, since they are conducted on the same soil, only the value obtained at 22°C was used.

Table 8.1.2-8: Normalised DT50 for amitrole (SFO kinetics)

Study	Soil	T (°C) study	Temperature correction factor (EA=65.4 kJ/mol)	Soil moisture measured in the study (g/100g soil)	Moisture during the study (% MWHC)	Moisture during the study (g/100g soil)	Reference moisture content at pF2 (g/100g soil)	Moisture correction factor	DT50 (days) from the study	DT50 (days) at 20°C, pF2
Hall (1994)	Group A (sand)	22	1.200	pF2.5 = 10.15	75% pF2.5	7.6	12	0.727	23.8	20.8
Jarczyk (1988a,b)	Soil 1	22	1.200	NM	NM	NM	NR	1	3.4	4.1
Jarczyk (1988c)	Soil 2	22	1.200	NM	NM	NM	NR	1	3.6	4.3
Jarczyk (1988c)	Soil 1	22	1.200	NM	NM	NM	NR	1	6.8	8.2

NM: not mentioned in the original report

NR: not reported since the texture of the soil is not available. As worst-case, no normalisation for moisture is performed.

B.8.1.2.1.2. Aerobic degradation of the active substance at 10° C

No data at 10°C was provided. However, an experiment in the study of Hall (1994) was conducted at 7°C, and thus gives an indication of the degradation rate of the active substance at low temperature. A DT50 of 87.2 days was obtained at 7 °C (see B.8.1.2.1.1 for details).

B.8.1.2.1.3. Aerobic degradation of relevant metabolites in soil

No metabolite was included in the risk assessment in the original DAR. In the framework of this re-assessment, 1,2,4-triazole was included in the risk assessment by the applicant. Common EU agreed endpoints exist for this metabolite, and no additional data was provided by the applicant.

The endpoints of 1,2,4-triazole are reported in B.8.1.3.

B.8.1.2.1.4. Photolytic degradation kinetics parameters of Amitrole in soil

No additional study was submitted, please refer to the DAR.

B.8.1.2.2. Field studies (annex IIA 7.1.1.2.2)**B.8.1.2.2.1. Stability of substance name in soils under frozen storage conditions**

No additional study was submitted, , please refer to the DAR.

B.8.1.2.2.2. Field dissipation studies

One field study (Hawkins *et al.*, 1982b) was mentioned in the addendum to the original DAR. The applicant was asked to provide a new kinetic assessment of these data according to FOCUS recommendations. When recalculating the DT50 of amitrole, the applicant also made reference to the study of Biever (1995). RMS checked that this study, although dated 1995, was not included in the original DAR. Therefore, it is summarised below.

Biever, R.C., 1995 – Amizol: A field dissipation study for terrestrial uses. SLI Report #93-10-4999.

- ☐ **Guidelines:** USEPA 164-1
- ☐ **GLP:** Yes
- ☐ **Deviations:** none identified
- ☐ **Acceptability:** Yes
- ☐ **Method**

A terrestrial dissipation study was conducted during 1993 to evaluate the persistence of amitrole and one of its degradates, cyanamide in soil. It was conducted with the commercial formulation Amizol at two geographically and climatically different areas in the northwestern portion of the United States. The first study site was located in Hillsboro, Oregon; the second one was located in Moses Lake, Washington.

Characterisation of the soils is reported in the following tables. The study sites had not received an application of Amizol for at least 5 years. A pesticide use history for the past 5 years was obtained for each study site. The analysis of the soils showed no pesticides not PCBs, except trace levels of DDE (0.01 mg/kg) for the Oregon site.

Table 8.1.2-9: Characterisation of soil collected from the Oregon treatment plot

Parameter	Depth (cm)					
	0-15	15-30	30-45	45-60	60-75	75-90
pH	5.8	5.8	5.7	5.6	5.8	5.8
Water holding capacity (%)	32.70	32.87	32.85	36.34	39.14	40.83
Textural composition						
Percent sand	24	20	14	14	16	18
Percent silt	50	52	52	50	50	54
Percent clay	26	28	34	36	34	28
Textural class	loam	silty clay loam	silty clay loam	silty clay loam	silty clay loam	silty clay loam
Percent organic matter	1.7	1.4	0.3	0.2	0.3	0.2
Bulk density (g/cm ³)	1.06	1.05	1.11	1.08	1.08	1.10
Cation exchange capacity (meq/100g)	8.8	9.1	10.6	13.7	16.2	18.1

Table 8.1.2-10: Characterisation of soil collected from the Washington treatment plot

Parameter	Depth (cm)					
	0-15	15-30	30-45	45-60	60-75	75-90
pH	6.8	7.1	7.8	8.3	8.6	8.6
Water holding capacity (%)	16.18	15.92	16.27	18.72	19.53	17.89
Textural composition						
Percent sand	48	50	50	42	42	46
Percent silt	42	42	42	52	52	48
Percent clay	10	8	8	6	6	6
Textural class	loam	loam	loam	silt loam	silt loam	sandy loam
Percent organic matter	1.3	1.3	0.7	0.7	0.5	0.5
Bulk density (g/cm ³)	1.29	1.29	1.31	1.30	1.29	1.33
Cation exchange capacity (meq/100g)	12.5	15.1	22.2	22.7	22.6	23.9

There were 2 test plots identified for each study site. The untreated control plot was approximately 0.02 ha and the treated plot was approximately 2 times the size of the control plot. Each control plot and treated plot were divided into 6 sampling zones of equal size.

Precipitation, air temperature and soil temperature (at depth of 7.5 cm and 30 cm for Oregon site; at depth of 7.5 cm for Washington site) were measured throughout the study. Monthly data are reported in Table 8.1.2-12. Ten years of historical weather data were obtained from the nearest weather stations. Information is summarised in the following table.

Table 8.1.2-11: Characterisation of soil collected from the Washington treatment plot

	Oregon site	Washington site
Range of annual rainfall	25-50 inches (640-1270 mm)	4-12 inches (100-310 mm)
10-year total average annual rainfall	33.59 inches (853 mm)	8.39 inches (213 mm)
10-year total average annual rainfall from June to October	6.06 inches (154 mm)	2.64 inches (67 mm)

Precipitation at the Oregon site was greater than the 10 year average for each month of the study. Natural precipitation was not adequate to support the water needs of other crops grown in the same field as the bare plots used in this study. As a result, an additional 430 mm of irrigation were applied. Precipitation at the Washington site was below the 10 year average from the period of June to October. To provide an average of at least 50 mm of water per month, there were also 260 mm of irrigation applied. Air temperature at both sites was similar to the 10 year historical data.

Table 8.1.2-12: Summarised air temperature, soil temperature and precipitation at both sites

Oregon							
Month	Air Temperature (°F)			Soil Temperature (°F)			Precipitation (in)
	mean ^a	min	max	mean ^a	min	max	Total
June	61.7	41.4	89.2	65.6	55.2	80.6	2.03
July	62.8	42.5	88.4	66.3	56.3	82.0	1.33
August	66.4	40.4	98.9	68.3	53.8	86.6	2.27
September	63.7	34.4	93.9	64.7	49.7	79.1	1.31
October	56.2	34.6	89.7	56.7	46.8	71.5	4.07
Total							11.01

Washington							
Month	Air Temperature (°F)			Soil Temperature (°F)			Precipitation (in)
	mean ^b	min ^c	max ^c	mean ^b	min ^c	max ^c	Total
June	65.3	54.9	76.4	71.1	60.7	81.0	0.36
July	67.1	61.8	77.3	76.5	71.3	81.7	0.60
August	69.0	57.8	78.2	75.9	67.7	83.4	0.32
September	60.5	46.7	72.5	65.5	52.9	77.2	0.13
October	50.5	35.9	67.0	53.0	40.9	65.6	0.15
Total							1.56

^a Means are calculated from the all of the daily minimum and maximum readings for the month.

^b Means are calculated from the daily average for the month.

^c Minimum and maximum temperatures are daily average minimum and maximum temperatures for the month.

On 3 May 1993, 30 days prior to application, a cover crop of Owens spring wheat was sown into the treated and control plots at the Oregon site. Thirteen days prior to test initiation, glyphosate was applied to both plots at 2.2 kg a.i./ha. One additional application was made at 1.1 kg a.i./ha 118 days after application. No other agricultural practices besides irrigation (see Table 8.1.2-13) were performed during the trial period.

In the fall of 1992 a cover crop of winter wheat was sown into the lot area at the Washington site for wind erosion control. Twenty-nine days prior to trial initiation, Roundup and Spray Booster S surfactant were applied at 1.2 L/ha. The plot area was maintained weed free with applications of Paraquat and Spray booster S surfactant at the rate of 1.2 L/ha 6 days prior to application and 37, 64, 93 and 109 days after application. No other agricultural practices besides irrigation (see Table 8.1.2-13) were performed during the trial period.

Table 8.1.2-13: Amount of irrigation and rainfall applied at each site

Oregon				
DAA	Date	Amount of Irrigation ^a		Total Water Received
		inches	mm	inches
23	25 June	1.48	37.6	
26	28 June	1.50	38.1	
	June Total	2.98	75.7	2.03
33	5 July	1.48	37.6	
39	11 July	1.49	37.8	
59	31 July	1.94	49.3	
	July Total	4.91	124.7	1.33
61	2 August	2.01	51.1	
77	18 August	1.48	37.6	
84	25 August	1.97	50.0	
	August Total	5.46	138.7	2.27
96	6 September	1.01	25.7	
113	23 September	2.46	62.5	
	September Total	3.47	88.2	1.31
	October Total	0.00	0.0	4.07

Washington				
DAA	Date	Amount of Irrigation ^b		Total Water Received
		inches	mm	inches
-3	14 June	1.50	38.1	
1	18 June	1.00	25.4	
	June Total	1.50	63.5	0.36
14	1 July	1.00	25.4	
19	6 July	0.25	6.4	
43	30 July	1.00	25.4	
	July Total	2.25	57.2	0.60
60	16 August	1.30	33.0	
	August Total	1.30	33.0	0.32
91	16 September	1.00	25.4	
102	27 September	1.00	25.4	
	September Total	2.00	50.8	0.13
110	5 October	1.00	25.4	
117	12 October	1.00	25.4	
	October Total	2.00	50.8	0.15

^a Values are a mean of two rain gauge readings.^b Values are a mean volume of five catch cups.

Amizol was applied once at each study site at the maximum labelled application rate of 9 kg/ha. For Oregon site, application was made on 2 June 1993. There was a 90% cloud cover. The air temperature was 18.9°C with a southwest wind of less than 3.2 km/h. The actual application rate was 9.170 kg a.i./ha.

The application was made on 17 June 1993 at Washington site, on a sunny clear day with an air temperature of 22.4°C. The winds were measured at 1.6-3.2 km/h out of the southwest. Soil temperature at a 7.6 cm depth was 21.1°C and the soil surface was moist but firm. The relative humidity of the air at the time of the application was measured at 72%. The actual application rate was 8.212 kg a.i./ha.

Five of the 6 zones were randomly selected and sampled from the treated plot and the control plot on the following sampling days:

- At Oregon site: -1, 0, 1, 3, 7, 14, 21, 29, 61, 89 and 124 days after treatment.

- At Washington site: -1, 0, 1, 3, 7, 14, 21, 30, 61, 92, 123, 131 days after treatment. The day 123 soil cores were damaged during shipping to laboratory and were not analysed.

Three composite soil samples were collected from the treated plot and one composite sample was collected from the control plot, at each sample depth increment and each sampling interval. Each composite soil sample included one core from each of five randomly selected sampling zones to give 5 soil cores per composite sample. The soil cores were taken to a depth of 90 cm in 2 increments: 0-15 cm and 15-90 cm. The 0-15 cm soil samples collected on day 0 were not composited, and were analysed separately in order to get a better estimate of the variability associated with the initial soil concentration. The soil cores from the control plot were always collected prior to collecting the soil cores from the treated plot. For analysis, the 15-90 cm were cut in 15 cm horizons. If residues were measured in the 15-30 cm, the 30-45 cm was also analysed. It continued until no quantifiable residue was identified.

In addition, the application was monitored by placement and analysis of 2 (one of top of the other) on-target spray cards in each zone of the treated plots and one drift card in each zone of the control plot. The application cards were impartially placed in each of the zones in both plots immediately prior to application. All deposition cards were retrieved after completion of application (approximately 30 minutes).

The analytes evaluated were amitrole and its potential metabolites cyanamide, aminoguanidine, urazole and 5-hydroxyamitrole. Reproducible and quantifiable recoveries from soil matrices were only achieved for amitrole and cyanamide.

Analysis of amitrole:

The LOQ for amitrole in both the Oregon and Washington soil matrices was 0.010 mg/kg. Mean recoveries of laboratory fortified quality control (QC) samples of amitrole were 63.7% and 63.4% for the 0.100 mg/kg and 1 mg/kg QC samples, respectively from the Oregon soil. Mean recoveries of amitrole were 90.7% and 86.9% for the 0.100 mg/kg and 1 mg/kg QC samples, respectively from the Washington soil. These results are similar to the initial recoveries from the amitrole method validation in soil: 68.9% for Oregon and 97.8% for Washington. Although amitrole recoveries from the Oregon site were less than 70%, the recoveries were consistent throughout the study and the same method consistently provided recoveries greater than 85% in Washington soils. The differences in extraction efficiency between the 2 sites is most likely a result of considerably different soil characteristics. A brief summary of the extraction and analysis is presented below.

A 50-g sample was placed into a 250 mL beaker with 100 mL of 10 mM KBr 80:20 methanol:water extraction solvent and sonic disrupted for 5 minutes at 80% output with a 50% duty cycle. The mixture was transferred to a 500 mL centrifuge bottle. The beaker was rinsed with methanol and the rinsate combined with the extract. The sample was centrifuged for 10 minutes at 2000 rpm. The supernatant was collected and filtered through a 0.7 micron glass microfiber filter and collected into a 1 L roundbottom flask. The soil sample was extracted a second time with 10 mM KBr 80:20 methanol:water extraction solution and the extracts combined into the roundbottom flask. The combined extract was rotary evaporated at 80°C to dryness, diluted with reagent grade water and submitted for analysis. Amitrole was analysed using reverse phase, isocratic HPLC with electrochemical detection. The confirmatory analysis of amitrole used reverse phase, isocratic HPLC with UV/VIS detection.

Analysis of cyanamide:

The LOQ for cyanamide in the Oregon soil was 0.010 mg/kg and in the Washington soil matrix was 0.025 mg/kg. Mean recoveries of cyanamide were 68.3% and 71.3% for the 0.100 mg/kg QC samples, respectively from the Oregon and Washington soils. The recoveries for the Washington soil QC samples were similar to the initial recoveries from the cyanamide method validation in soil: 73.0%. The recoveries from the cyanamide QC samples fortified in the Oregon soil were slower than those observed in the initial method validation but much less variable: 92.1%. A brief summary of the extraction and analysis is presented below.

A 50-g soil sample and 100 mL of acetone were added to a 200 mL centrifuge bottle. The bottle was capped and briefly shaken by hand before being placed on a shaker table for 30 minutes at 250 rpm. The sample was then centrifuged for 10 minutes at 150 rpm and allowed to settle. A 2 mL sample of the supernatant was transferred to a 15 mL graduated centrifuge tube and evaporated to dryness under a gentle stream of nitrogen. A derivatization procedure followed, when the remaining residues were dissolved into 1 mL of a 1 mg/mL solution of dansyl chloride (in acetone) and 1 mL of 4 mM Na₂CO₃/46 mM NaHCO₃ buffer solution (pH 9). The sample was vortexed for ca 30 seconds and heated for 1 hour at 50 °C. the solution was then cooled and submitted to HPLC analysis. Dansyl-cyanamide was analysed using reverse phase, gradient elution HPLC with fluorescence detection.

Findings

The recovery of amitrole from the application cards from the Oregon site was about half of the expected recovery, ranging between 31.5 to 69.1% of the nominal application rate, with a mean of 52.2%. The recovery of amitrole from the application cards from the Washington site were near the nominal application rate, ranging between 79.2 to 94.6%. The application card procedures between both sites were identical from deployment through analysis and the difference between recoveries cannot be readily explained.

The recoveries of total amitrole residues in soil immediately following applications were similar at both study sites. The mean total residues from the Oregon site was 60.4% of the nominal application rate, with the 15 samples between 27.0 and 95.9%. The mean total residues from the Washington site was 63.0% of the nominal application rate, with the 15 samples between 31.5 and 78.8%.

Results of soil samples analysis are presented in the following table.

Table 8.1.2-14: mean measured concentrations of amitrole, cyanamide and total residue in soil samples

Days after application	Sample depth (cm)	Residue (mg/kg)					
		Oregon			Washington		
		Total	Amitrole	Cyanamide	Total	Amitrole	Cyanamide
0	0-15	1.79	1.77	0.01	2.52	2.50	0.01 ^a
1	0-15	1.50	1.47	0.02	1.37	1.34	0.01
3	0-15	1.31	1.29	0.01	1.06	1.04	0.01
7	0-15	1.74	1.74	BLOQ	1.02	1.01	0.01
14	0-15	0.64	0.64	BLOQ	1.23	1.23	BLOQ
21	0-15	0.92	0.92	BLOQ	0.39	0.37	0.01
30 ^b	0-15	0.42	0.42	BLOQ	0.37	0.37	BLOQ
61	0-15	0.08	0.08	BLOQ	0.35	0.35	BLOQ
90 ^b	0-15	0.03	0.03	BLOQ	0.08	0.08	BLOQ
120 ^b	0-15	0.01	0.01	BLOQ	0.01	0.01	BLOQ
0	15-30	BLOQ	BLOQ	BLOQ	BLOQ	BLOQ	BLOQ
1	15-30	BLOQ	BLOQ	BLOQ	BLOQ	BLOQ	BLOQ
3	15-30	BLOQ	BLOQ	BLOQ	BLOQ	BLOQ	BLOQ
7	15-30	BLOQ	BLOQ	BLOQ	BLOQ	BLOQ	BLOQ
14	15-30	BLOQ	BLOQ	BLOQ	BLOQ	BLOQ	BLOQ
21	15-30	BLOQ	BLOQ	BLOQ	BLOQ	BLOQ	BLOQ
30 ^b	15-30	BLOQ	BLOQ	BLOQ	BLOQ	BLOQ	BLOQ
61	15-30	BLOQ	BLOQ	BLOQ	0.03	0.03 ^c	BLOQ
90 ^b	15-30	BLOQ	BLOQ ^d	BLOQ	BLOQ	BLOQ	BLOQ
120 ^b	15-30	BLOQ	BLOQ	BLOQ	BLOQ	BLOQ	BLOQ
61	30-45	NA	NA	NA	BLOQ	BLOQ	NA
90 ^b	30-45	BLOQ	BLOQ	NA	NA	NA	NA

BLOQ Below limit of quantification, NA Not applicable.

^aValue shown is a mean of thirteen out of fifteen samples, cyanamide was not detected in the remaining two samples.

^bSamples collected on the following days: OR Days 29, 89, and 124, WA Days 30, 92, and 131.

^cValue shown is a mean of two out of three samples, the third sample was BLOQ.

^dOne sample concentration was 0.01 mg/kg and the other two samples were BLOQ.

The maximum amitrole soil concentrations occurred on day 0 at both study sites. Decline after 7 days was rapid with concentrations at the LOQ by day 124 and 131 in Oregon and Washington, respectively. Amitrole was rarely detected or quantified in any soil horizon below 15 cm. Cyanamide appeared immediately in the 0-15 cm soil horizon at both sites, with maximum concentrations at day 1 and dissipated quickly. Cyanamide concentrations between 0.01 and 0.02 mg/kg were measured in the 0 to 15 cm soil horizon from day 0 to day 3 at the Oregon site and just detected from day 0 to day 21 at the Washington site. Quantifiable concentrations were never found in a soil horizon below 15 cm.

❑ Comments from RMS

The study is considered acceptable. Although not required since amitrole degrades quickly in laboratory, it confirms its rapid degradation. Amitrole is rarely found below 15 cm, suggesting limited movement in soil. It has to be noted that both sites are located in the US. The amount of water at Oregon site (including irrigation) is particularly high.

Comoretto, L., 2012a – Estimating persistence and degradation kinetics from environmental fate studies on Amitrol. Document No: NUFkinetic31082012.

❑ **Guidelines:** FOCUS 2006

❑ **GLP:** Not relevant

❑ **Deviations:** Yes, see comments

❑ **Acceptability:** Partly acceptable

❑ Method

Data from field study presented in the original DAR (Hawkins, 1982b) and from the additional study of Bieber (1995) were re-assessed to derive new DT50 according to FOCUS Kinetic guidance document. The excel spreadsheet FOCUS_DEGKIN_v2 was used. SFO kinetic was tested for each soil. When considered necessary, FOMC kinetic was also tested.

Raw data from Hawkins *et al.* (1982) were taken into account. For Bieber (1995), the applicant transformed the data from mg/kg to % considering initial concentrations of 5.225 mg/kg for Oregon and 3.889 mg/kg for Washington.

Data used from the study of Hawkins *et al.* (1982b) summarised in the original DAR are reported below. Data from Bieber (1995) are available in the above summary.

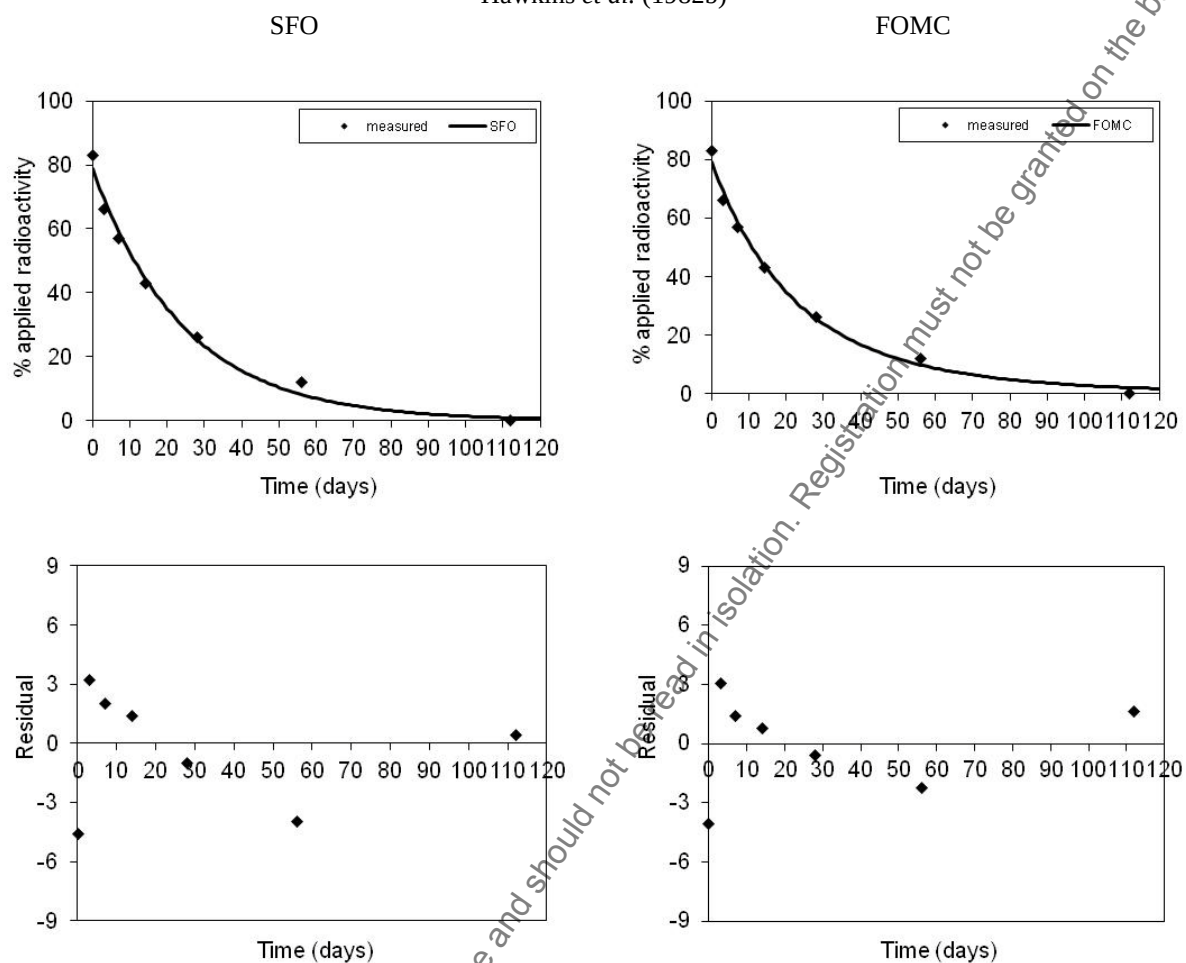
Table 8.1.2-15: Percentage recovery of radioactivity – Hawkins et al., 1982b

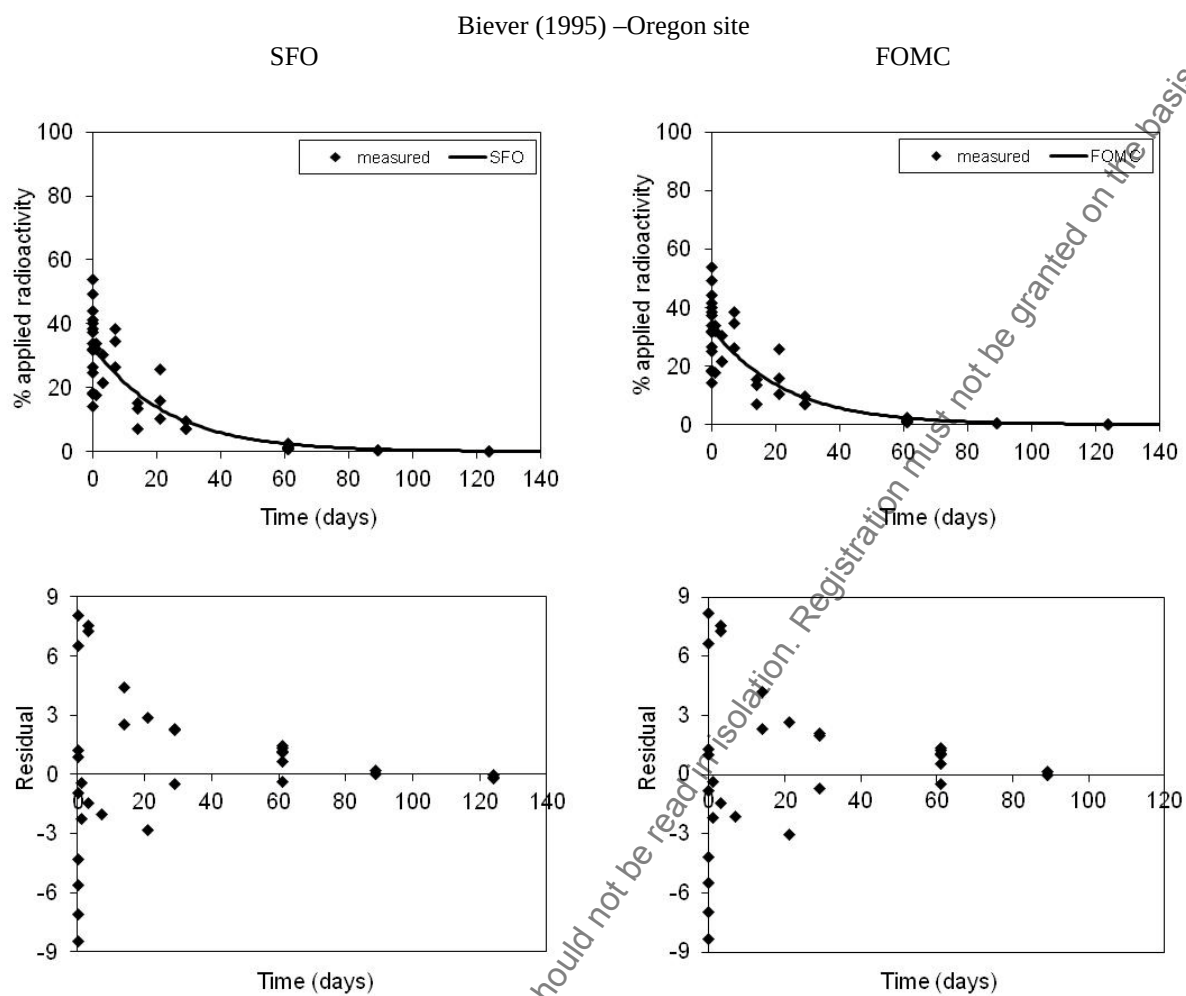
Time after application (days)	Depth of analysed layer (cm)	Extracts expressed of applied radioactivity
0	0 -5	83.2
3	0 -5	66.4
7	0 -5	57.2
14	0 -5	43.2
28	0 -5	26.3
56	0 -5	12.1
112	0 -5	0.4

❑ Findings

Visual fits and residual plots obtained for each soil with SFO and FOMC models are presented below.

Hawkins *et al.* (1982b)





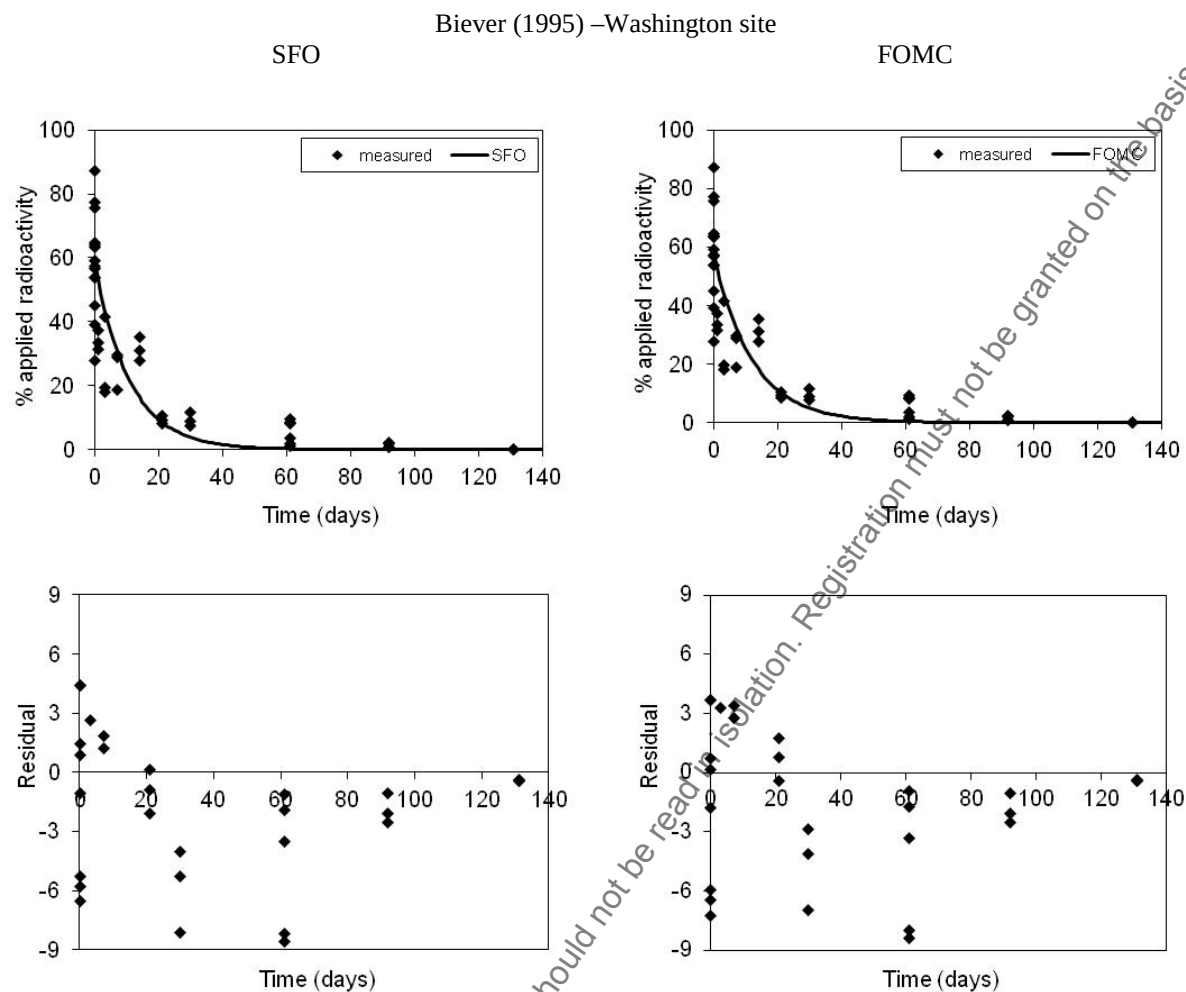


Figure 8.1.2-3: Visual fits and residual plots for Amitrole degradation

Kinetic parameters and χ^2 are reported in the table below.

Table 8.1.2-16: Kinetic parameters

Soil	Model	Kinetic parameters	χ^2	DT50 (days)	DT90 (days)
Hawkins <i>et al.</i> (1982b)	SFO	$k=0.040$	3.1	17.1	56.9
	FOMC	$\alpha=6.490$ $\beta=148.1$	3.1	16.7	63.1
Biever (1995) Oregon site	SFO	$k=0.043$	28.0	16.1	53.4
	FOMC	$\alpha=310.832$ $\beta=7037.3$	28.5	15.7	52.3
Biever (1995) Washington site	SFO	$k=0.091$	31.5	7.6	25.4
	FOMC	$\alpha=576.29$ $\beta=7025.5$	32.1	8.5	28.1

❑ Comments from RMS

The applicant did not provide any clear conclusion on the acceptability of the fits in the study. For each soil, it is not specified whether SFO or FOMC is selected. No statistical parameters except the χ^2 were provided.

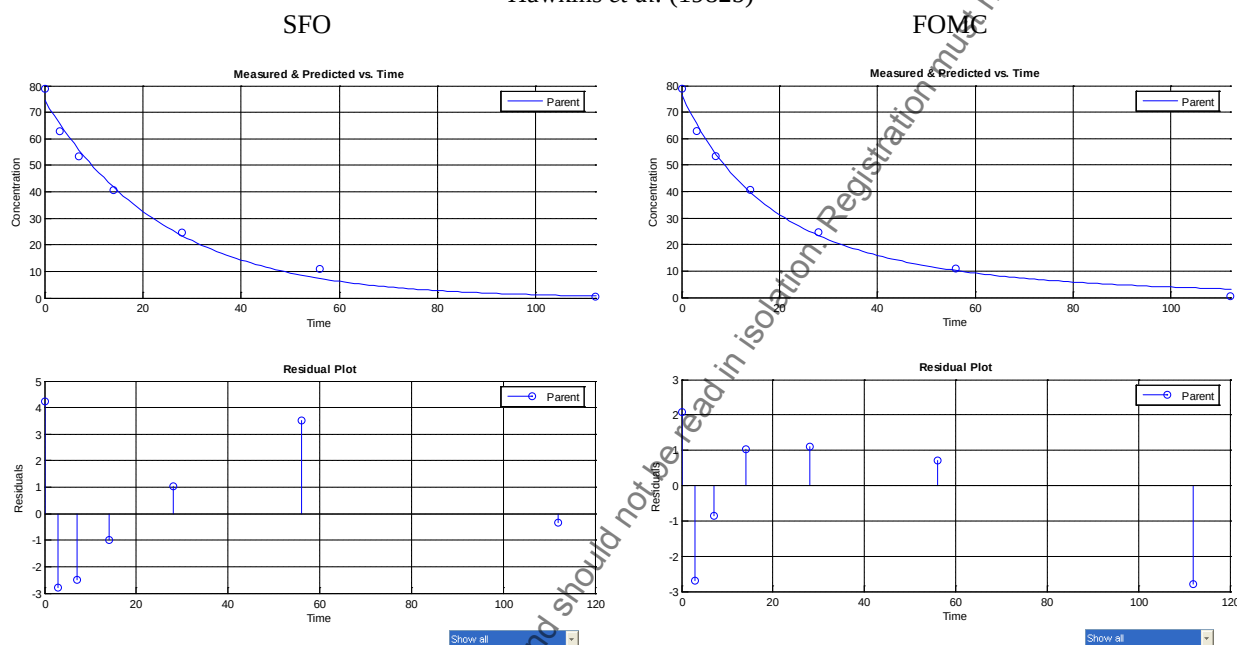
In addition, when checking the raw data from the study of Hawkins *et al.* (1982b), it appeared that the applicant used the total extractable radioactivity to derive DT50 values instead of the radioactivity corresponding to extractable amitrole. Therefore, the calculations proposed are not accepted.

For data from Bieber (1995), the kinetic analysis performed by the applicant was checked and is considered acceptable. The transformation of the data from mg/kg to % is not strictly correct, however since the same transformation was made for each sampling point, it has no impact on the results obtained. The kinetic analysis was completed by RMS since t-test or confidence intervals were not reported in the study. RMS used results from the study expressed in mg/kg.

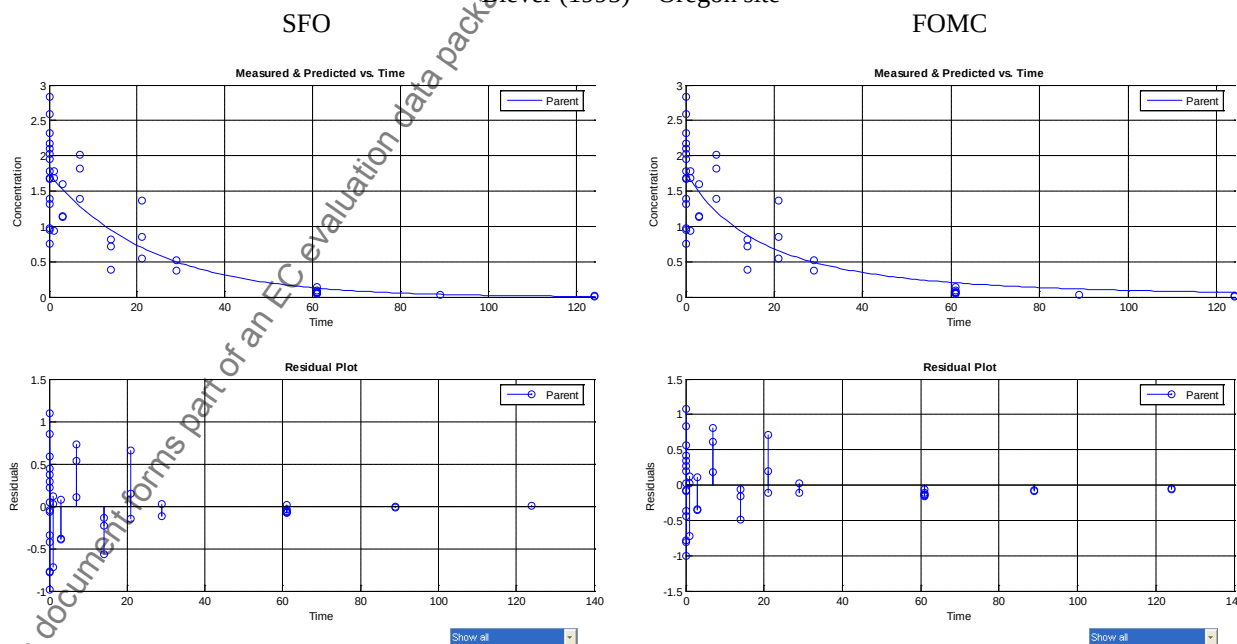
The kinetic analysis was performed using the software KinGUI 1.0. SFO and FOMC models were tested for each soil. The best kinetic was selected based on visual fits, residual plots, χ^2 value, t-test and confidence interval. Since Amitrole was rarely measured below 15 cm, only results from the 0-15 cm were used.

Visual fits and residual plots are presented below.

Hawkins *et al.* (1982b)



Biever (1995) – Oregon site



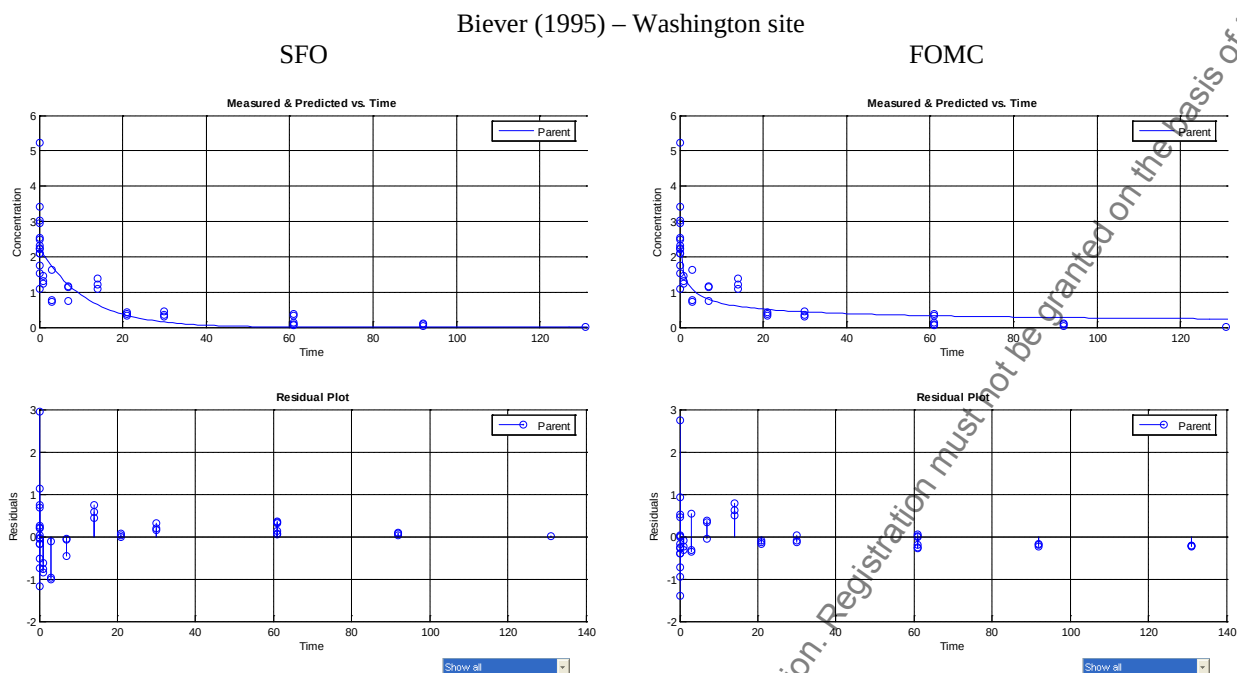


Figure 8.1.2-4: Visual fits and residual plots for Amitrole degradation

Kinetic parameters and statistical results are reported in the following table.

Table 8.1.2-17: Kinetic parameters and statistical results

Study	Soil	Model	Kinetic parameters	χ^2	t-test	0 included in confidence interval Y/N	DT50 (days)	DT90 (days)
Biever (1995)	Oregon site	SFO	$k=0.0431$	16.5	$1.4e-5$	N	16.1	53.4
		FOMC	$\alpha=2.3422$ $\beta=40.039$	18.5	-	α : Y β : Y	13.8	67.0
	Washington site	SFO	$k=0.0905$	26.0	$4.9e-4$	N	7.7	25.4
		FOMC	$\alpha=0.4151$ $\beta=0.4637$	17.2	-	α : N β : Y	2.0	118.5
Hawkins <i>et al.</i> (1982b)	Huntington	SFO	$k=0.0413$	5.3	$4e-5$	N	16.8	55.8
		FOMC	$\alpha=2.8059$ $\beta=53.2098$	4.0	-	α : Y β : Y	14.9	67.7

For Oregon and Huntington sites, SFO gave good visual fits, acceptable χ^2 value, and the kinetic parameters are significant. FOMC does not improve significantly the fits. Therefore, SFO was selected.

For Washington site, SFO gives acceptable fits but with a high χ^2 value. FOMC gives a better χ^2 value, however the kinetic parameter are not significant. In addition, the visual fit is not significantly improved. It is therefore proposed to keep the SFO model. Although a χ^2 value higher than 15% is obtained, it is considered that it can be accepted for field studies.

B.8.1.2.2.3. Soil accumulation testing

No additional study was submitted, not required since Amitrole is not persistent.

B.8.1.3. Summary on route and rate of degradation in soil

The route of degradation of Amitrole under aerobic laboratory conditions was investigated in 3 studies. Two of them (Hawkins *et al.*, 1982a and Scholz *et al.*, 1988) had already been submitted in the original DAR. As explained under B.8.1.1.1, both studies had been accepted although they presented some deviations. An additional study (Hall, 1994), not reported in the original DAR is summarised under B.8.1.1.1 and considered acceptable. This study confirms the degradation pathway that had been proposed in the original DAR. Amitrole is rapidly degraded by microbial activity into CO₂. Depending on the studies, mineralisation reaches 20-60% AR after 7 days (Hawkins *et al.*, 1982a) or 44.5% AR after 91 days (Hall, 1994). Non extractable residues are also important, reaching 20-50% after 7 days (Hawkins *et al.*, 1982a) or 40.89% AR after 91 days. No major metabolites were quantified. Degradation should proceed via 5-hydroxyaminotriazole rapidly degraded to cyanamide then urea. A secondary pathway leads to urazole. Only urazole, cyanamide, urea and aminoguanidine bicarbonate are found in trace amounts in soil. RMS noted that some unidentified radioactivity reaches levels above 10% on some occasions in the study of Hall (1994). RMS highlights that the HPLC reference standard of 1,2,4-triazole was used in the study, therefore it is not expected that this unknown radioactivity corresponds to 1,2,4-triazole. This should be confirmed by the applicant. **The applicant should also clarify whether the unidentified radioactivity is formed by several compounds or not and whether each compound exceeds 5% AR or not.** The applicant indicated at the end of December 2012 that this point was currently being checked.

Under sterile conditions, amitrole degrades at slower rate. Mineralisation is negligible (*ca* 1% AR after 365 days) and bound residues are formed (50.6% AR after 7 days in Hawkins *et al.*, 1982a and 41.8% AR after 91 days in Hall, 1994).

The route of degradation of Amitrole is presented on the following Figure.

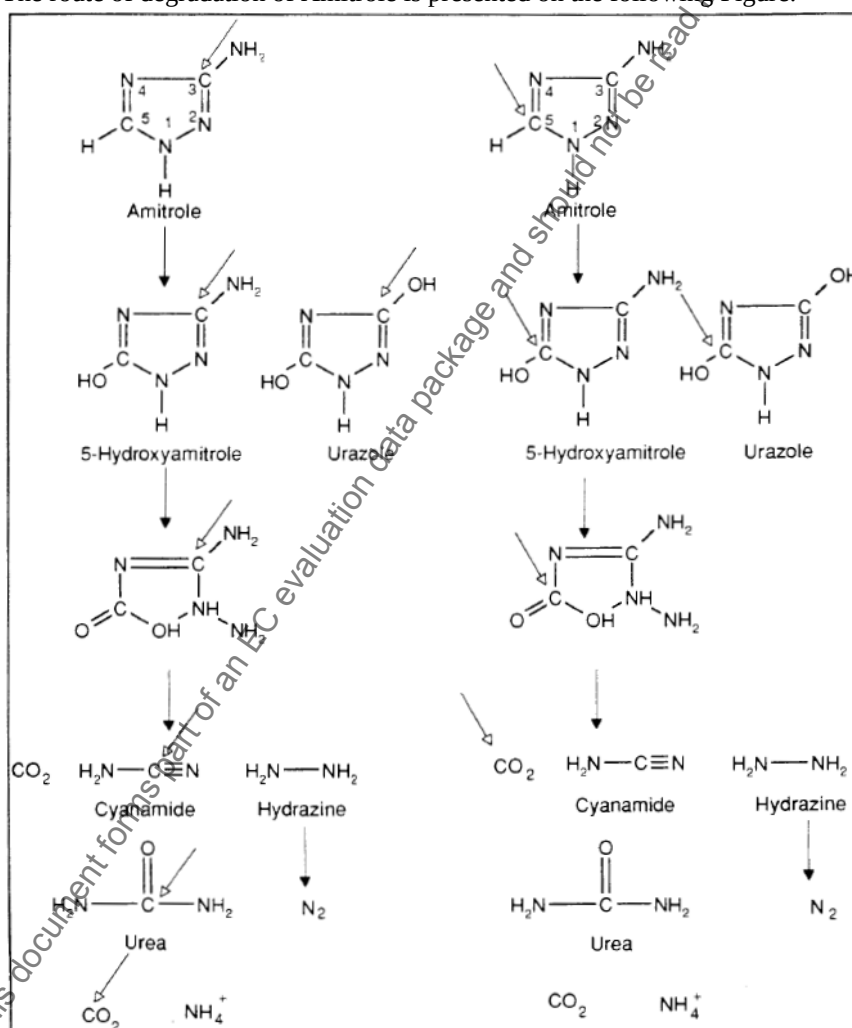


Figure 8.1.3-1: Degradation pathway of Amitrole in soil

No new study on degradation of amitrole under anaerobic conditions was provided. Amitrole is degraded at a slower rate than under aerobic conditions, and still represents 28.5% AR after 112 days (19.8% AR after 364 days). Non-extractable residues reached a maximum of 61.4% AR after 112 days (65.7% AR after 224 days) and volatiles were negligible (<0.6% AR after 112 days). Amitrole was the major compound identified in the extractable radioactivity, other components were minor (one reached a maximum of 6.2% AR after 28 days, others did not exceed 5% AR).

Among the 2 studies provided in the original DAR to investigate photodegradation, only one (Das, 1990) was considered as reliable. Amitrole was more degraded in the irradiated samples (Xenon lamp, 300-800 nm, 500 Watt/m², 12 h photoperiod) than in dark controls: after 30 days irradiation, amitrole represented 66.4% AR against 88.7% in dark controls. The rate of degradation of amitrole under irradiated conditions was estimated by linear first-order regression to 73 days. The only degradation product was 1,2,4-triazole, exceeding 5% from day 3 and increasing up to 9.9% at the end of the experiment (30 days). In dark controls, 1,2,4-triazole was detected at each sampling date, and reached a maximum of 4.1% AR after 21 days.

1,2,4-triazole was included in the risk assessment for soil, surface water and groundwater by the applicant for all intended uses. RMS notes that according to the sustained GAP for agricultural uses (application period), photodegradation is not expected to be a major route of degradation of amitrole in soil and therefore 1,2,4-triazole is not expected to be formed in significant amounts. Therefore, to the RMS opinion, a risk assessment was not strictly required. However, RMS considers that if further agricultural uses occurring when photodegradation may be important would be sustained, it should be discussed whether 1,2,4-triazole may need to be included in the risk assessment or not. It is highlighted that photodegradation and microbial degradation will be concomitant and concurrent processes. Therefore, if photodegradation occurs in field, the maximum occurrence reached is expected to be lower than 9.9%.

The rates of degradation of Amitrole under laboratory aerobic conditions and field conditions have been updated according to FOCUS Kinetics (2006). In addition, DT₅₀ from additional studies compared to the original DAR are available. Amitrole follows single first-order degradation. In laboratory under aerobic conditions, DT₅₀ ranged between 3.4 days to 23.8 days (n=4). Normalised DT₅₀ to 20°C and pF 2 ranged between 4.1 to 20.8 days (geometric mean: 7.4 days). Values from 3 field sites (one in UK, 2 in US) are also available. They ranged between 7.7 and 16.8 days.

Table 8.1.3-1: DT₅₀ values of amitrole under laboratory aerobic conditions

Laboratory studies ‡

Parent	Aerobic conditions						
Soil type	X ¹	pH	t. °C / % MWHC	DT ₅₀ / DT ₉₀ (d)	DT ₅₀ (d) 20 °C pF2/10kPa	St. (χ ²)	Method of calculation
Sand		6.2	22°C / 75% pF2	23.8/79.1	20.8	6.7	SFO
Standard 2.1		6.5	22°C / nr	3.4/11.2	4.1	17.6	SFO
Standard 2.2		6.1	22°C / nr	3.6/11.9	4.3	11.3	SFO
Standard 2.3		5.5	22°C / nr	6.8/22.5	8.2	4.3	SFO
Sand		6.2	7°C / 75% pF2	87.2/289.7	-	4.8	SFO
Geometric mean					7.4		

¹ X This column is reserved for any other property that is considered to have a particular impact on the degradation rate.

Table 8.1.3-2: DT50 values of amitrole under field conditions

Field studies ‡

Parent	Aerobic conditions								
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	X ¹	pH	Depth (cm)	DT ₅₀ (d) actual	DT ₉₀ (d) actual	St. (χ ²)	DT ₅₀ (d) Norm.	Method of calculation
Loam (cropped)	Oregon (USA)		5.8	90	16.1	53.4	16.5	-	SFO
Loam (cropped)	Washington (USA)		6.8	90	7.7	25.4	26.0		SFO
Loam (bare)	Huntington (UK)		7.6	40	16.8	55.8	5.3	-	SFO
Geometric mean								-	

For 1,2,4-triazole, common agreed endpoints were specified during PRAPeB 12 (2007). These endpoints were recently updated by CRD in the following document: “Triazole Derived Metabolite: 1,2,4-Triazole - Proposed revision to DT50 - Summary, Scientific Evaluation and Assessment - July 2011, revised September 2011 (after comments from MS and EFSA)”. These new endpoints are used in the risk assessment. They are presented below.

Table 8.1.3-3: DT50 values of 1,2,4-triazole under laboratory aerobic conditions

Laboratory studies

1,2,4-triazole (applied as parent)	Aerobic conditions						
Soil type	X ²	pH	t. °C / % MWHC	DT ₅₀ fast phase/DT ₅₀ slow phase(d)/g	DT ₅₀ (d) 20°C pF2/10kPa	St. (r ²)	Method of calculation
Sandy loam		6.4	20 °C / 40 %	0.9/59.2/0.683			DFOP
Loamy sand		5.8	20 °C / 40 %	1.5/247.6/0.580			DFOP
Silt loam		6.2	20 °C / 40 %	0.8/20.6/0.443			DFOP
Geometric mean				1.0/67.1/0.569			DFOP

X This column is reserved for any other property that is considered to have a particular impact on the degradation rate.

Table 8.1.3-4: DT50 values of 1,2,4-triazole under field conditions

Field studies ‡

1,2,4-triazole (applied as parent)	Aerobic conditions, kinetics calculated for ambient conditions . Bare soil with grass sown immediately after application (with exception of Spain site where no grass sown).								
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	X ¹	pH	Depth (cm)	DT ₅₀ (d) actual	DT ₉₀ (d) actual	St. (χ ²)	DT ₅₀ (d) Norm	Method of calculation
Silt loam	Germany		6.4	0-30	7.8	366.7	15.2		FOMC
Silty clay loam	Italy		7.6	0-40	21.2	207.4	10.7		DFOP
Sandy loam	UK		7.4	0-40	6.8	109.3	17.8		DFOP
Loam	Spain		5.8	0-30	28.1	717.6	13.3		DFOP
Geometric mean/median									
1,2,4-triazole (applied as parent)	Aerobic conditions, kinetics calculated timestep normalised to 20°C and pF2 moisture . Bare soil with grass sown immediately after application (with exception of Spain site where no grass sown).								
Soil type	Location		pH	Depth (cm)	DT ₅₀ (d) Fast phase	DT ₅₀ (d) Slow phase	'g'	St. (χ ²)	Method of calculation
Silt loam	Germany		6.4	0-30	2.5	70.7	0.655	18.8	DFOP
Silty clay loam	Italy		7.6	0-40	1.4	59.8	0.364	10.6	DFOP
Sandy loam	UK		7.4	0-40	0.5	25.1	0.458	18.1	DFOP
Loam	Spain		5.8	0-30	4.6	126.0	0.489	12.7	DFOP
Geometric mean ('g' value is arithmetic mean)					1.68	60.5	0.489		DFOP

B.8.2. ADSORPTION, DESORPTION AND MOBILITY IN SOIL (ANNEX IIA 7.1.2 AND 7.1.3, ANNEX IIIA 9.1.2)**B.8.2.1. Adsorption and desorption of the active substance (annex IIA 7.1.2)**

Adsorption of Amitrole was studied in the studies of Huhtanen (1985) and Anderson & Hellpointner (1989) in the original DAR. Both studies were found acceptable and used in the risk assessment, and were not re-assessed. Results are summarised in B.8.2.6.

One new study (Meinerling & Herrmann, 2012) is also provided by the applicant. It is summarised below.

Meinerling, M., Herrmann, S., 2012 – Determination of the adsorption/desorption behaviour of amitrole (XT 91) [OECD 106]. Project 70821195.

❑ **Guidelines:** OECD 106

❑ **GLP:** Yes

❑ **Deviations:** percentage of radioactivity < 20% for 1 soil; some 1/n values are not in the usual range

❑ **Acceptability:** Partly acceptable

□ Method

Adsorption/desorption of amitrole (purity 91.3%) in soil was investigated in a batch equilibrium study on 6 soils at 20°C in the dark. Soil characteristics are reported in the following table.

Table 8.2.1-1: Soil characteristics

Soil	LUFA 2.1	LUFA 6S	LUFA 2.4	Eurosoil 1	Eurosoil 5
Texture	Sand	Clay	Loam	Clay	Loamy sand
Grain size (<0.002 mm)	3.0/2.7	42.1/41	27.2/26.9	-	-
Grain size (0.002-0.05 mm)	8.8/10.1	36.0/36.8	40.6/40.3	-	-
Grain size (0.05-2 mm)	88.2/87.3	21.9/22.2	32.2/32.8	-	-
Grain size (<0.0002 mm)	-	-	-	75.0	6.0
Grain size (0.0063-0.0002 mm)	-	-	-	8.2	1.0
Grain size (0.02-0.0063 mm)	-	-	-	9.7	4.3
Grain size (0.02-0.063 mm)	-	-	-	4.0	7.4
Grain size (0.063-0.2 mm)	-	-	-	1.3	6.8
Grain size (>0.2 mm)	-	-	-	2.0	64.8
pH (CaCl ₂)	5.1	7.2	7.2	5.7	3.1
OC (%)	0.81/0.62	1.75/1.64	2.99/2.42	3.27	5.96
CEC (mval/100 g)	4/3.8	22.6/23.7	33.6/29.3	-	-

Preliminary experiments (preliminary test and screening test) were conducted to determine the conditions of the definitive experiment; including the optimal soil-to-solution ratio (established to be 1:2.5), test substance stability (stable at a concentration of at least 5 mg/L), adsorption of test substance to test vessels (negligible) and adsorption and desorption equilibrium times (48 hours).

For the definitive experiment, 2 g soil in combination with 5 mL aqueous solution was used. The stock solution was diluted using 0.01 M CaCl₂ to a concentration of 10, 25 and 100 mg/L. For soil A to C the tested concentrations were 0.1 mg/L, 0.25 mg/L, 0.5 mg/L, 1.0 mg/L, and 1.5 mg/L. For soil B the tested concentrations were 0.1 mg/L, 0.25 mg/L, 0.5 mg/L, 1.0 mg/L, and 2.5 mg/L. For soil D and E the tested concentrations were 0.5 mg/L, 1.0 mg/L, 2.5 mg/L, 5.0 mg/L, and 10.0 mg/L.

The mixtures were agitated for the maximum recommended time of 48 h. After this time period samples were taken. The suspension was centrifuged to separate the solid and liquid phase (10 min 3000 rpm) to obtain a clear solution. The aqueous phase was analysed by LC-MS/MS.

Control samples containing only the test item solution (without soil) were subjected to precisely the same steps as the test system, in order to check the stability of the test item in CaCl₂ solution and its possible adsorption on the surface. For the desorption step no control was required. One blank run per soil with the same amount of soil and total volume of CaCl₂ solution were subjected to the same test procedure. This served as a background control during the analysis to detect interfering compounds or contaminated soils.

After the equilibration time of 48 h the solid and liquid phases were separated by centrifugation. The aqueous phase was removed to the greatest extent possible. The volume of CaCl₂ removed was replaced by an equal volume of fresh 0.01 M CaCl₂. The new mixtures were agitated again and samples were taken applying a parallel method after 48 h. The aqueous phases were recovered after centrifugation (10 min 3000 rpm) and analysed by test item specific LC-MS/MS analysis.

□ Findings

The analysis of the control samples showed that adsorption of the test item to the test system was negligible. The test item did not adsorb to filtration units and thus filtration step could be performed. Analyses of control samples confirmed that the test item was stable under the test conditions.

The mass balance during the screening test ranged between 70 and 107% for all soils except Eurosoil 5, which had a mass balance of 61%.

The percentage of adsorption calculated for each soil and concentration is reported in the following table. In case of soil LUFA 2.4 the adsorption was below 10%; in case of other soils, the adsorption value was in the range of 24 to 101%. Values for soil LUFA 2.4 are therefore excluded.

Table 8.2.1-2: percentage of adsorption in each soil

Concentration of test item in solution (mg/L)	Percentage of adsorption (%) (mean of replicates)				
	LUFA 2.1	LUFA 6S	LUFA 2.4	Eurosoil 1	Eurosoil 5
0.1	57.6	54.6	7.4	-	-
0.25	51.0	52.8	0.6	-	-
0.5	40.3	48.9	-4	84.2	101
1.0	24.0	45.8	5.4	97.4	96.3
1.5	33.3	-	2.2	-	-
2.5	-	37.8	-	97.6	95.2
5.1	-	-	-	81.3	68.0
10.1	-	-	-	76.5	59.1

Adsorption exponents for soil A, B, D and E were in the range of KFads of 1.0 to 11.4. The slope of the isotherms was in the range of 0.3 to 0.8 indicating non-linear sorption behaviour. KF values were related to the organic carbon content. The adsorption coefficients were calculated as mean values of the apparent coefficient. The results are summarized in the following table.

Table 8.2.1-3: Freundlich parameters for amitrole

Soil	OC (%)	pH (CaCl ₂)	Kf (mL/g)	Kfoc (mL/g)	1/n	r ²
LUFA 2.1	0.62	5.1	1.0	159	0.590	0.938
LUFA 6S	1.64	7.2	1.9	114	0.808	0.996
LUFA 2.4	2.42	7.2	0.0	2	0.857	0.302
Eurosoil 1	3.27	5.7	11.2	341	0.476	0.638
Eurosoil 5	5.96	3.1	8.7	146	0.326	0.895

□ RMS comments

RMS agrees that results from soil LUFA 2.4 should be excluded since percentage of adsorption is below 20% and the plot for isotherm adsorption is very bad. Percentages of adsorption from other soils respect the guideline. However, the adsorption isotherm for Eurosoil 1 cannot be accepted since the regression coefficient is not good enough ($r^2=0.638$, plot visually not satisfactory). In addition, the 1/n parameters for soils LUFA 2.1, Eurosoil 1 and Eurosoil 5 are questionable, since they are far from the usual range of 0.7-1.0 mentioned in the guideline. Therefore, RMS is of the opinion that the only reliable adsorption parameters are the ones obtained for soil LUFA 6S: $K_{foc} = 114 \text{ mL/g}$ and $1/n = 0.808$.

RMS also notes that for PEC_{sw} and PEC_{gw} calculations, the applicant only used the values from soil LUFA 6S. He did not provide any explanation, but RMS assumes that the applicant also considered that the values obtained on the other soils were not acceptable.

B.8.2.2. Adsorption and desorption of relevant metabolites (annex IIA 7.1.2)

No metabolite was included in the risk assessment in the original DAR. In the framework of this re-assessment, only 1,2,4-triazole has been included in the risk assessment. Common EU agreed endpoints exist for this metabolite, and no additional data was provided by the applicant. The endpoints of 1,2,4-triazole are reported in B.8.2.6.

B.8.2.3. Column leaching studies (annex IIA 7.1.3)

No additional study was submitted, please refer to the DAR.

B.8.2.4. Aged residue column leaching (annex IIA 7.1.3.2)

No additional study was submitted, please refer to the DAR.

B.8.2.5. Lysimeter studies (annex IIA 7.1.3.3)

No additional study was submitted, please refer to the DAR.

B.8.2.6. Summary on the mobility of amitrole and its relevant metabolites in soil

Adsorption of Amitrole was investigated in 3 batch adsorption studies (2 studies provided in the original DAR and one new study) that give reliable adsorption parameters for 9 soils covering a range of pH values (5.3-7.4), organic carbon content (0.5-3.4%) and clay content (2-42.7%). K_{foc} of Amitrole ranged between 20 and 202 mL/g, with 1/n between 0.65 and 0.87. According to McCall classification, Amitrole exhibits medium to very high mobility in soil.

Please note that K_{foc} from the study of Huhtanen (1985) (first four soils in the following table) were corrected by RMS since they were initially calculated using the organic matter content instead of the organic carbon content.

Adsorption parameters of 1,2,4-triazole were agreed in PRAPeR 12. They were investigated on 4 soils. K_{foc} ranged between 43 and 120 mL/g, with 1/n between 0.83 and 1.02. According to McCall classification, 1,2,4-triazole exhibits high to very high mobility in soil.

Table 8.2.6-1: Adsorption parameters of Amitrole

Parent ‡							
Soil Type	OC %	Soil pH	K _d (mL/g)	K _{oc} (mL/g)	K _f (mL/g)	K _{foc} (mL/g)	1/n
Sandy loam	1.74	6.1 (un)			3.52	202	0.65
Silt loam	3.42	6.8 (un)			3.79	111	0.77
Silty clay loam	2.9	7.0 (un)			1.57	54	0.86
Sand	0.46	5.6 (un)			0.685	149	0.80
Silty clay	0.64	7.4 (CaCl ₂)			0.714	112	0.77
Sandy loam	0.75	6.8 (CaCl ₂)			0.223	30	0.85
Sand	0.75	5.6 (CaCl ₂)			0.152	20	0.87
Silt	1.8	5.3 (CaCl ₂)			0.921	51	0.86
Clay	1.64	7.2 (CaCl ₂)			1.9	114	0.81
Arithmetic mean/median					1.50/0.92	94/111	0.80/0.81
pH dependence, Yes or No			No				

(un): matrix of pH measurement unknown

Table 8.2.6-2: Adsorption parameters of 1,2,4-triazole

Metabolite 1,2,4-triazole							
Soil Type	OC %	Soil pH (CaCl ₂)	K _d (mL/g)	K _{oc} (mL/g)	K _f (mL/g)	K _{foc} (mL/g)	1/n
Silty clay	0.70	8.8			0.83	120	0.897
Clay loam	1.74	6.9			0.75	43	0.827
Silty clay loam	0.70	7.0			0.72	104	0.922
Sandy loam	0.81	6.9			0.72	89	1.016
Arithmetic mean/median					0.76	89	0.92
pH dependence (yes or no)			No				

Mobility of Amitrole was also studied on 2 soils in a column leaching study, provided in the original DAR. Radioactivity in the leachates reached 24-31% AR in the first soil, and was 0.8% in the second soil. In the first-soil, most of the radioactivity in the leachates corresponded to the parent Amitrole.

B.8.3. PREDICTED ENVIRONMENTAL CONCENTRATIONS IN SOIL (PEC_s) (ANNEX IIIA 9.1.3)

Amitrole can be used for agricultural uses and non crop uses (on permeable and impermeable surfaces). PEC_{soil} are calculated in the same way for agricultural uses and non crop uses on permeable surfaces. For non crop uses on impermeable surfaces, PEC_{soil} calculation is not considered relevant.

Amitrole is applied either once per year at 2977 g/ha or several times at lower rates but respecting the maximum application rate / year of 3000 g/ha, with 2-3 months interval between applications.

For PEC_{soil} calculations, it is assumed that Amitrole is applied at the maximum rate of 2977 g as/ha in a single application every year as worst-case. Amitrole is an herbicide and therefore is not directed to the crop but to the ground. The applicant noted that amitrole it not applied on bare soil but on well developed weeds (growth stage 40-60), and therefore used an interception value of 90%.

RMS does not agree with this value since the cover by weeds may be very different from a case to another. In addition, the interception by weeds is usually not taken into account in PEC calculations. The standard practice for these kinds of uses is to use a worst-case interception value of 0%. This value is used in the RMS calculations reported below.

PEC_{soil} were calculated according to FOCUS Soil guidance document, assuming a soil depth of 5 cm and a soil bulk density of 1.5 g/cm³.

The standard practice is to use the longest DT50 value from field studies. However in the case of amitrole; field data from 3 sites only are available (2 of which located in US), which is not considered sufficient. Therefore, the longest laboratory DT50 value of 28.6 days (SFO) was used (the longest laboratory DT50 of 23.8 days measured at 22°C is normalised to 20°C using a Q10 of 2.58; this results in a DT50 value of 28.6 days at 20°C).

For 1,2,4-triazole, the worst-case field DT50 value was used. According to the latest agreed endpoints on 1,2,4-triazole, this corresponds to: DT50 = 28.1 days, from a DFOP kinetic ($k_1 = 0,002 \text{ day}^{-1}$, $k_2 = 0,0632 \text{ day}^{-1}$, $g = 0,573$). The application rate was corrected by a maximum occurrence in soil of 9.9% and by molecular ratio, as proposed by the applicant.

It is noted that the DT50 used for 1,2,4-triazole is obtained from a study where 1,2,4-triazole is applied. Therefore, the use of the combination of maximum occurrence observed with this kind of DT50 is not strictly correct (it can leads to an underestimation of the PEC). However, in this case where 1,2,4-triazole is only formed by photodegradation, it is considered that it can be acceptable (since amitrole is rapidly degraded by soil micro-organisms, it is expected that the maximum occurrence of 9.9% will not be reached under field conditions. Therefore, the maximum occurrence may be used as formation fraction in this case). It is also reminded that RMS considers that 1,2,4-triazole is not expected to be formed in significant amounts for the sustained uses and

does not need to be assessed (see B.8.1.3). Calculations are reported for information since 1,2,4-triazole was included in the risk assessment by the applicant.

Amitrole is not considered as persistent, and therefore no plateau concentration was calculated. However, 1,2,4-triazole can be considered as persistent (DT90 of 717.6 days). A plateau concentration was calculated in 5 cm (background value in 5 cm + PECsoil,ini in 5 cm).

A summary of the calculations is given below.

Table 8.2.6-1: Summary of PECsoil calculations for Amitrole

Parent Amitrole
Method of calculation

DT₅₀ (d): 28.6 days (the longest laboratory DT₅₀ of 23.8 days measured at 22°C is normalized to 20°C using a Q10 of 2.58, resulting in a DT₅₀ value of 28.6 days at 20°C)
Kinetics: SFO
Field or Lab: representative worst case from laboratory studies (at 20°C).

Application data

Crop: orchards, grapes, olives, non crop uses
Depth of soil layer: 5cm
Soil bulk density: 1.5g/cm³
% plant interception: No interception
Number of applications: 1
Interval (d): -
Application rate(s): 2977 g as/ha

PEC_(s)
(mg/kg)

Initial

Short term 24h

2d

4d

Long term 7d

21 d

28d

50d

100d

Plateau
concentration

Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
3.969		-	
3.874	3.922	-	-
3.782	3.875	-	-
3.603	3.783	-	-
3.350	3.651	-	-
2.386	3.111	-	-
2.014	2.882	-	-
1.182	2.301	-	-
0.352	1.493	-	-
No accumulation expected			

Table 8.2.6-2: Summary of PECsoil calculations for 1,2,4-triazole

Metabolite 1,2,4-triazole	Molecular weight relative to the parent: 69.1/84.08			
Method of calculation	DT ₅₀ (d): 28.1 days Kinetics: DFOP (parameters: $k_1 = 0,002 \text{ day}^{-1}$, $k_2 = 0,0632 \text{ day}^{-1}$, $g = 0,573$) Field or Lab: representative worst case from field studies.			
Application data	Application rate assumed: 242 g as/ha (assumed 1,2,4-triazole is formed at a maximum of 9,9 % of the applied dose and molecular ratio of 69.1/84.08)			
PEC _(s) (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.323		-	
Short term 24h	0.314	0.318	-	-
2d	0.306	0.314	-	-
4d	0.290	0.306	-	-
Long term 7d	0.271	0.295	-	-
21 d	0.214	0.257	-	-
28d	0.198	0.244	-	-
50d	0.173	0.218	-	-
100d	0.152	0.189	-	-
Plateau concentration	0.494 mg/kg after 8 yrs (in 5 cm)			

B.8.4. FATE AND BEHAVIOUR IN WATER (ANNEX IIA 7.2.1, ANNEX IIIA 9.2.1 AND 9.2.3)**B.8.4.1. Hydrolysis**

No additional study was submitted, please refer to the DAR for details. A summary of fate and behaviour in water is provided in B.8.4.4.

B.8.4.2. Photodegradation in water

No additional study was submitted, please refer to the DAR for details. A summary of fate and behaviour in water is provided in B.8.4.4.

B.8.4.3. Biological degradation**B.8.4.3.1. Ready biodegradability**

No study was available in the original DAR. The following additional study has been provided.

Feil-Klein, N., 2012 – Ready biodegradability of Amitrole (XT 91) in a manometric respirometry test. Project 70822163.

- ❑ **Guidelines:** OECD 301F
- ❑ **GLP:** Yes
- ❑ **Deviations:** None identified
- ❑ **Acceptability:** Yes
- ❑ **Method**

The purpose of this study was to determine the ready biodegradability of the test item Amitrole (XT 91). The test item (purity: 91.3%) was exposed to aerobic activated sludge from the aeration tank of a domestic waste water treatment plant for 28 days. The biodegradation was followed by the oxygen uptake of the microorganisms during exposure. As a reference item, sodium benzoate was tested simultaneously under the same conditions as the test item, and functioned as a procedure control.

The test flasks were prepared according to the following table. The amounts of test item and reference item were directly weighed into the test flasks. No emulsifiers or solvents were used, but the solutions were dispersed by stirring to achieve a homogeneous solution of the test item.

Table 8.4.3-1: Preparation of the test solutions

Treatment	Flask	Test item mg	Reference item ¹ mg	HgCl ₂ mL	Activated sludge ² mL	Test water mL	Final volume mL
Amitrole (XT 91)	1	24.9	-	-	5	239	244
	2	25.4	-	-	5	239	244
Inoculums control ³	3	-	-	-	5	239	244
	4	-	-	-	5	239	244
Procedure control ⁴	5	-	24.9	-	5	239	244
Abiotic control ⁴	6	25.1	-	5	-	239	244
Toxicity control	7	25.1	25.5	-	5	239	244

¹ Reference item: sodium benzoate

² Stock suspension of 1.5 g/L on dry matter base (final concentration: 29 g/L)

³ The inoculums control and the procedure control were also used for other projects which ran in parallel

⁴ Poisoned with HgCl₂ (stock solution of 48.84 mg/mL)

The closed test flasks were incubated in the dark at 22±1°C in a climatized room under continuous stirring. The pressure decrease in the reaction vessels was measured daily over complete experimental phase of 28 days using the BSB Sensomat system, Aqualytic Dortmund. The test flasks were closed gas-tight by a measuring head. Potassium hydroxide solution (45%) was used for trapping the produced carbon dioxide. The amount of O₂ consumed by the activated sludge was calculated from the decrease of pressure in the reaction vessel.

❑ Findings

Validity criteria of the study:

The oxygen demand of the inoculums control (medium and inoculums) was 30 mg O₂/L and thus not greater than 60 mg O₂/L within 28 days as required by the test guideline.

The pH-value of the test item flasks at the end of the test was 6.8-7.5 and therefore within the range of pH 6.0 to 8.5 as required by the test guideline.

The percentage degradation of the reference item should reach the level for ready biodegradability (>60%) within 14 days as required by the test guideline. The reference item sodium benzoate was degraded to more than 60% after 3 days of incubation.

The biodegradation did not reach 60% degradation within the 10-day window. At the end of the experiment, the difference in replicate variation was 0%.

Biodegradation of test item: The test item amitrole contains nitrogen, therefore the evaluation of biodegradation is based on $\text{ThOD}_{\text{NO}_3}$ (Theoretical Oxygen Demand with Nitrification). The criterion for ready biodegradability under the conditions of a manometric respirometry test is the 10-day window, describing the period during which between at least 10% degradation and 60% degradation is reached. This period should not exceed 10 days. The mean biodegradation after 28 days was 0% ($\text{ThOD}_{\text{NO}_3}$). Therefore, the 10-day window was not passed, and amitrole is not considered ready biodegradable.

Biodegradation of sodium-benzoate: The reference item sodium benzoate was sufficiently degraded to 85% after 14 days and to 85% after 28 days of incubation, thus confirming the suitability of the aerobic activated sludge inoculums used.

Biodegradation of the toxicity control: In the toxicity control containing both the test item and the reference item sodium benzoate, 27% biodegradation was noted within 14 days and 28% biodegradation after 28 days of incubation. Thus the test item can be assumed to be not inhibitory to the aerobic activated sludge micro organisms.

WARNING: This document forms part of an EC evaluation data package and should not be read in isolation. Registration must not be granted on the basis of this document.

Table 8.4.3-2: Cumulative biochemical oxygen demand (mg O₂/L) in test flasks

Time (days)	Flask No.						
	1	2	3	4	5	6	7
1	0	0	0	0	55	0	0
2	0	0	5	5	80	0	25
3	0	0	5	10	110	0	65
4	0	0	5	10	120	0	75
5	5	5	5	10	130	0	95
6	5	5	10	10	140	0	115
7	5	5	10	15	145	0	125
8	5	5	10	15	145	0	130
9	10	10	15	15	150	0	135
10	10	10	15	15	155	0	135
11	10	10	15	15	155	0	135
12	15	10	20	15	160	0	140
13	15	15	20	20	160	0	140
14	15	15	20	20	165	0	145
15	15	15	20	20	165	0	145
16	15	20	25	20	170	0	150
17	20	20	25	25	170	0	150
18	20	20	25	25	170	0	150
19	20	20	25	25	170	0	150
20	20	20	25	25	170	0	150
21	20	20	25	25	170	0	155
22	20	20	25	25	170	0	155
23	20	25	25	25	170	0	155
24	25	25	25	25	170	0	155
25	30	25	25	25	175	0	155
26	30	30	30	30	175	0	160
27	30	30	30	30	175	0	160
28	30	30	30	30	175	0	160

Flasks 1 and 2: Amitrole (X491)
 Flasks 3 and 4: inoculum control
 Flask 5: reference (procedure control)
 Flask 6: abiotic control
 Flask 7: toxicity control

Table 8.4.3-3: Percentage biodegradation of test item, of sodium benzoate and of the toxicity control

Time (Days)	Percentage Biodegradation					
	Amitrole (XT 91) ¹		Sodium Benzoate ²		Toxicity control ^{1,2}	
	Flask 1 [%]	Flask 2 [%]	Flask 5 [%]		Flask 7 [%]	
			ThOD _{NH4}	ThOD _{NO3}	ThOD _{NH4}	ThOD _{NO3}
1	0	0	32	32	0	0
2	-2	-2	44	44	4	4
3	-3	-3	60	60	13	13
4	-3	-3	66	66	15	15
5	-1	-1	72	72	19	19
6	-2	-2	76	76	23	23
7	-3	-3	78	78	24	24
8	-3	-3	78	78	26	26
9	-2	-2	79	79	26	26
10	-2	-2	82	82	26	26
11	-2	-2	82	82	26	26
12	-1	-3	84	84	27	27
13	-2	-2	82	82	26	26
14	-2	-2	85	85	27	27
15	-2	-2	85	85	27	27
16	-3	-1	87	87	28	28
17	-2	-2	85	85	27	27
18	-2	-2	85	85	27	27
19	-2	-2	85	85	27	27
20	-2	-2	85	85	27	27
21	-2	-2	85	85	28	28
22	-2	-2	85	85	28	28
23	-2	0	85	85	28	28
24	0	0	85	85	28	28
25	2	0	88	88	28	28
26	0	0	85	85	28	28
27	0	0	85	85	28	28
28	0	0	85	85	28	28

¹ ThOD_{NO3} of Amitrole (XT 91): 2.779 mg O₂/mg test item² ThOD_{NH4}/ThOD_{NO3} of sodium benzoate: 1.666 mg O₂/mg reference item**□ Conclusion**

Amitrole was found to be not readily biodegradable under the conditions of the test.

□ Comments from RMS

The study is acceptable.

B.8.4.3.2. Degradation in water sediment system (annex IIA 7.2.1.3.2)**B.8.4.3.2.1. Degradation in aerobic water sediment systems**

No additional study was submitted, please refer to the DAR for details. However, the applicant was asked to provide a new kinetic assessment of the data provided in the original DAR according to FOCUS recommendations. It is summarised below.

Comoretto, L., 2012a – Estimating persistence and degradation kinetics from environmental fate studies on Amitrol. Document No: NUFkinetic31082012.

- ❑ **Guidelines:** FOCUS 2006
- ❑ **GLP:** Not relevant
- ❑ **Deviations:** None identified
- ❑ **Acceptability:** Yes
- ❑ **Method**

Data from the water/sediment study presented in the original DAR (Scholz, 1995) were re-assessed to derive new DT50 according to FOCUS Kinetic guidance document. The excel spreadsheet FOCUS_DEGKIN_v2 was used. SFO kinetic was tested for each system, for water phase, sediment phase and total system. For water and sediment, dissipation rates were calculated (level P-I).

Raw data from Scholz, 1995 were taken into account without any change. They are summarised below. For sediment in Ijzendoorn system, only data from maximum occurrence were taken into account (from day 7).

Table 8.4.3-4: Percentage recovery of radioactivity (% AR) – Scholz, 1995 – Ijzendoorn system

Sampling date (days)	Water	Sediment	Total system
0	86.3	3.3	89.6
0	87.2	4.6	91.8
3	70.0	11.0	81.0
3	70.2	10.9	81.1
7	61.7	13.5	75.2
7	61.1	14.4	75.5
14	56.6	12.7	69.3
14	54.9	13.6	68.5
30	48.9	10.4	59.3
30	48.6	10.1	58.7
60	44.8	10.9	55.7
60	40.3	10.4	50.7
91	34.1	8.6	42.7
91	31.5	8.3	39.8

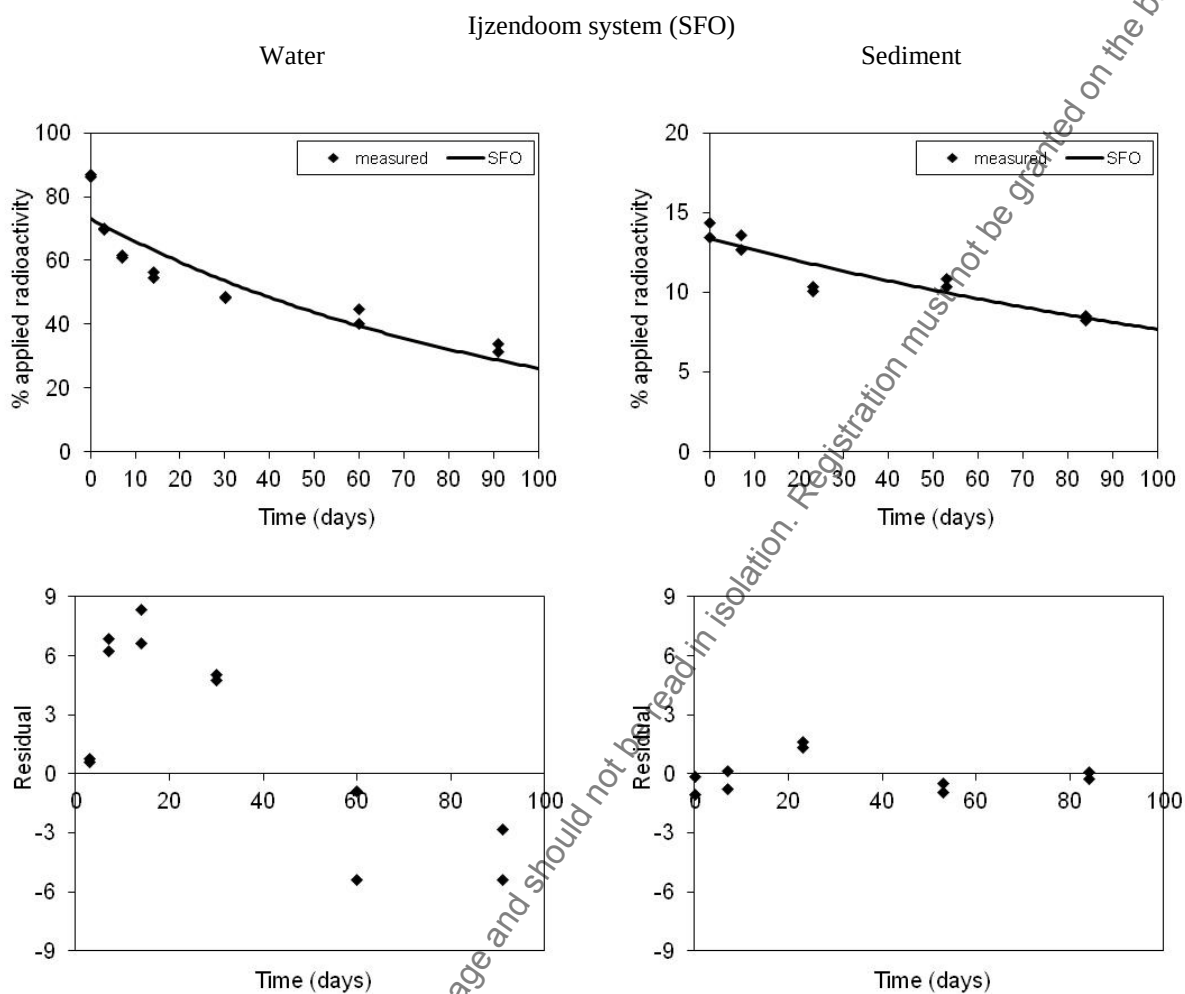
Table 8.4.3-5: Percentage recovery of radioactivity (% AR) – Scholz, 1995 – Lienden system

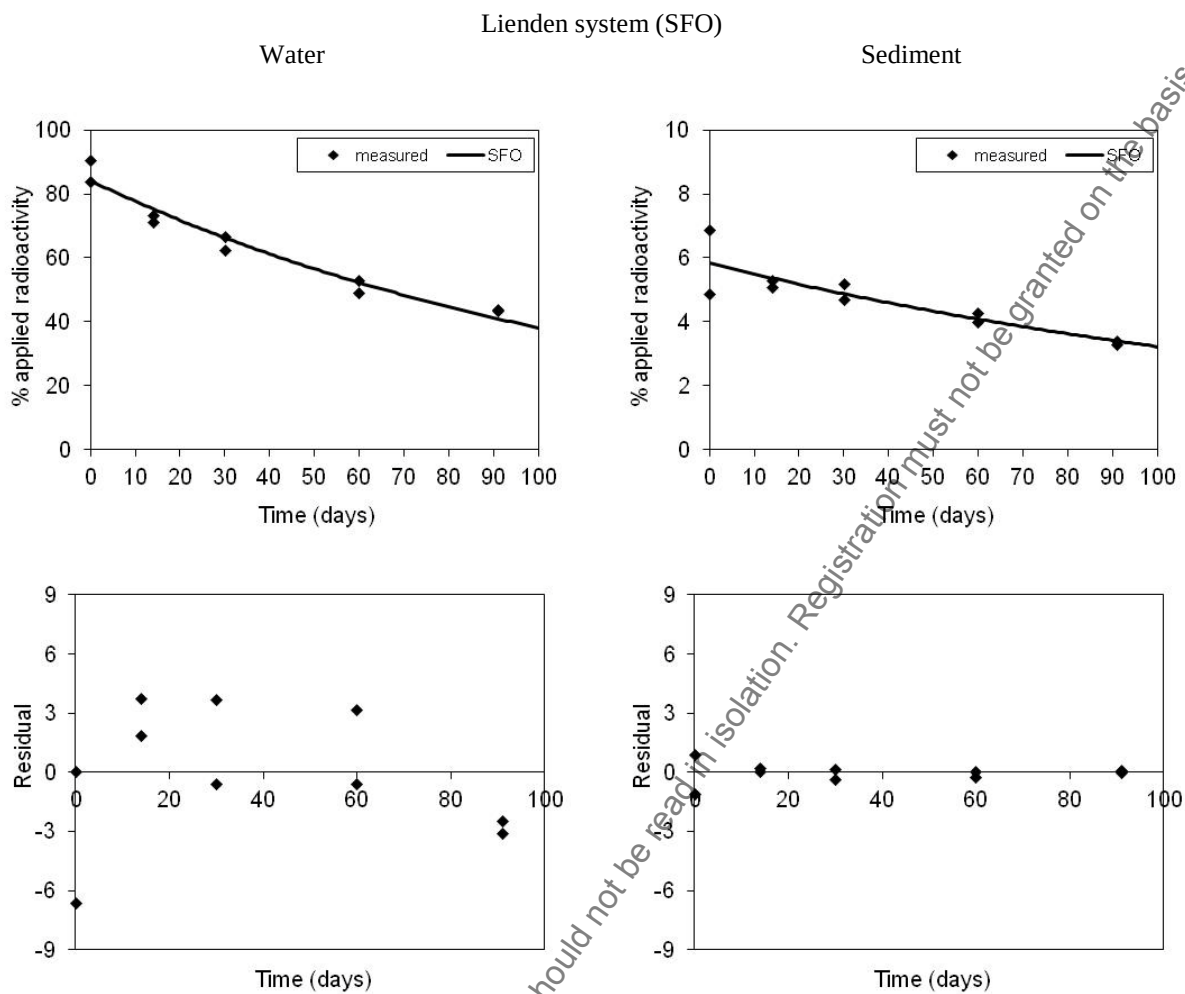
Sampling date (days)	Water	Sediment	Total system*
0	84.0	6.9	90.9
0	90.7	4.9	95.6
14	71.5	5.3	76.6
14	73.4	5.1	78.2
30	62.6	4.7	66.8
30	66.9	5.2	71.8
60	49.1	4.3	53.2
60	52.9	4.0	56.7
91	44.0	3.3	47.1
91	43.4	3.4	46.6

RMS notes that results do not strictly correspond to water + sediment values. However, the slight differences identified are not expected to impact on the results. This is confirmed by the additional kinetic analysis performed by RMS.

Findings

Visual fits and residual plots obtained for each system are presented below.





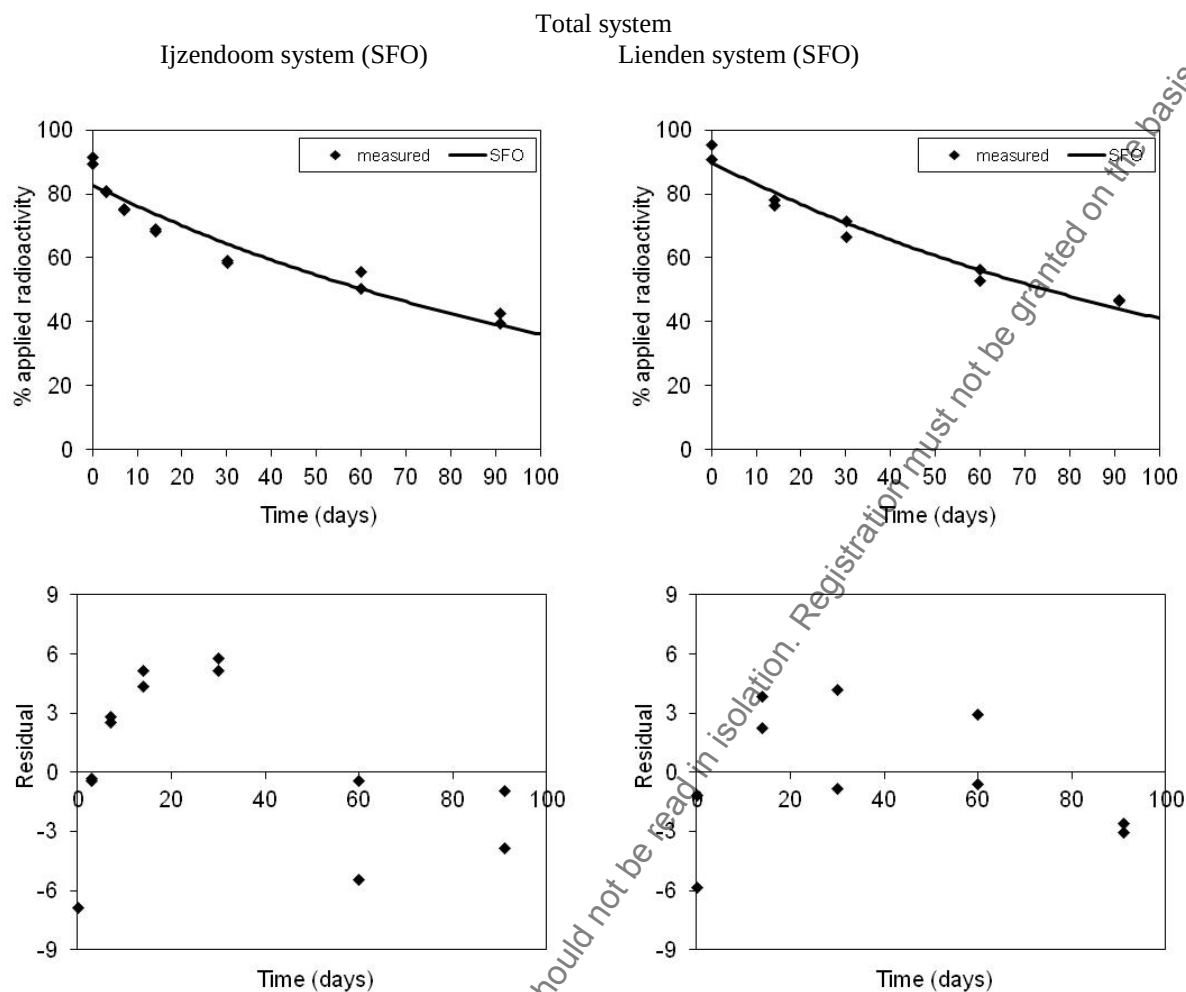


Figure 8.4.3-1: Visual fits and residual plots for Amitrole degradation

Kinetic parameters and χ^2 are reported in the table below.

Table 8.4.3-6: Kinetic parameters

System	Compartment	Model	Kinetic parameters	χ^2	DT50 (days)	DT90 (days)
Ijzendoorn	Water	SFO	k=0.010	9.7	67.6	224.5
	Sediment	SFO	k=0.006	5.7	124.8	414.6
	Total	SFO	k=0.008	5.3	83.6	277.6
Lienden	Water	SFO	k=0.008	3.1	87.6	291.1
	Sediment	SFO	k=0.006	1.6	116.8	388.2
	Total	SFO	k=0.008	3.0	88.7	294.5

□ Comments from RMS

No conclusion on the acceptability of the fits is proposed by the applicant. The calculations were checked by RMS and are found acceptable. Since no statistical parameters except the χ^2 were provided, RMS completed the applicant's kinetic analysis with KinGUI by reporting the t-test and indicating whether 0 is in the confidence interval or not. Results are reported below. DT50 values are in agreement with the ones proposed by the applicant.

RMS notes that for Ijzendoorn system, a biphasic model would have been more appropriate to describe the degradation/dissipation in water and total system. However, SFO can be considered sufficiently acceptable to be used for modelling. Results from the applicant are selected as agreed endpoints.

Table 8.4.3-7: Kinetic parameters and statistical results

System	Compartment	Model	Kinetic parameters	χ^2	t-test	0 included in confidence interval Y/N	DT50 (days)	DT90 (days)
Ijzendoorn	Water	SFO	k=0.0103	9.7	2.1e-5	N	67.6	224.6
	Sediment	SFO	k=0.0056	5.7	2.3-e4	N	124.8	414.6
	Total	SFO	k=0.0083	5.3	2.0e-7	N	89.6	277.6
Lienden	Water	SFO	k=0.0078	2.9	2.3e-7	N	88.5	294.1
	Sediment	SFO	k=0.0059	1.6	6.4e-4	N	116.8	388.2
	Total	SFO	k=0.0078	2.9	3.6e-7	N	89.3	296.5

B.8.4.3.2.2. Degradation in anaerobic water sediment systems

The following studies were provided. It is noted that degradation in water/sediment systems under anaerobic conditions is not a EC data requirement. These studies are reported as additional information and are not used in the risk assessment.

McCowan C., Mackie K. A. and Hall B. E., 1995 – The anaerobic degradation of radiolabelled amitrole in a natural water and its associated sediment. Inveresk Research International report n°382817.

- ❑ **Guidelines:** US-EPA 162-3
- ❑ **GLP:** Yes
- ❑ **Deviations:** None identified
- ❑ **Acceptability:** Yes
- ❑ **Method**

The objective of this study was to measure the rate of degradation of [^{14} C]-amitrole (radiochemical purity: 98%, specific activity: 228 μ Ci/mg) in an aquatic system (a freshly collected sample of sandy loam sediment and its associated natural water) over 52 weeks under anaerobic conditions at 22°C (viable and sterile samples) and 7°C (viable samples). The pattern of radiolabelled degradation products was also investigated at 22°C (viable samples).

Table 8.4.3-8: Sediment and water characterisation

Characteristic	Sediment	Water
pH	5.9	7.8
% OC	1.8	nr
CEC (meq/100 g soil)	8.89	nr
Texture	Sandy loam	nr
Clay (< 2 μ m)	10.6	nr
Silt (2-63 μ m)	13.8	nr
Very fine sand (63-125 μ m)	17.4	nr
Fine sand (125-250 μ m)	30.5	nr
Medium sand (250-500 μ m)	21.2	nr
Coarse sand (500-1000 μ m)	5.6	nr
Very coarse sand (1000-2000 μ m)	0.9	nr

nr: not relevant

Sediment samples (70; ca 24 g each) were weighed into individual borosilicate glass containers (id. = 4.5 cm) and associated water (ca 150 g) was added to each container. A stream of moist, oxygen-free nitrogen was introduced into the test system via a dip tube extending to just below the surface of the water. The test system was pre-incubated in the appropriate temperature range for 35-41 days in the dark to allow anaerobic conditions

to develop. Maintenance of these conditions throughout the study was monitored by total viable bacteria estimations and measuring redox potential.

Dose formulation (1 mL), containing 1.27 mg of [^{14}C]-amitrole (equivalent to a field application rate of 8 kg/ha), was applied to the surface of the associated water in each unit from Groups A to D ([^{14}C]-amitrole was added to incubation group C in a laminar flow cabinet under sterile conditions). Aliquots (1 mL) of dose formulation were dispensed into volumetric flasks (100 mL capacity) at regular intervals throughout the dosing period. These doses were made up to volume with methanol and aliquots (3 x 100 μL) submitted for liquid scintillation counting in order to determine the dose application. The radioactive application was 13.90 μCi per unit. The units in Groups E to H were dosed with a similarly prepared solution of non-radiolabelled amitrole (1 mL; 1.30 mg).

The test system is described in the following table.

Table 8.4.3-9: Test system design

Study Group	N° of Incubates	Flask number	Test system conditions	Treatment	Incubation temperature	Composition of ^{14}C absorbent	Sampling interval
A	28	1-28	Viable	[^{14}C]-Amitrole	$22 \pm 2^\circ\text{C}$	Individual ethanolamine	Days 0, 1, 3, 7, 10, 14, 21 and 30 – weeks 39 and 52
B	4	29-32	Viable	[^{14}C]-Amitrole	$22 \pm 2^\circ\text{C}$	Individual sodium hydroxide	weeks 39 and 52
C	8	33-40	Sterile	[^{14}C]-Amitrole	$22 \pm 2^\circ\text{C}$	Individual ethanolamine	Days 30 – weeks 13, 26 and 52
D	14	41-54	Viable	[^{14}C]-Amitrole	$22 \pm 2^\circ\text{C}$	Bulk ethanolamine	Days 0, 1, 3, 7, 10, 14, 21 and 30 – weeks 8, 13, 26 39 and 52
E	10	55-64	Viable	Amitrole	$22 \pm 2^\circ\text{C}$	None	Pre-dosing, day 30 weeks 13, 26 and 52
F	10	65-74	Viable	Amitrole	$7 \pm 2^\circ\text{C}$	None	Pre-dosing, day 30 weeks 13, 26 and 52
G	2	75-76	Viable	Amitrole	$22 \pm 2^\circ\text{C}$	None	52 weeks (control units for redox readings)
H	2	77-78	Viable	Amitrole	$7 \pm 2^\circ\text{C}$	None	52 weeks (control units for redox readings)

Following sampling, the surface water was decanted from each incubation unit. Each sediment residue was transferred to an amberlite jar, ethanol:water (1:1, by volume; ca 30 mL) added and the samples extracted immediately or stored at ca -20°C pending analysis. Each sediment sample was shaken for 1 h using a wrist action shaker. After shaking, the sediment was separated from the extract by centrifugation (1000 r.p.m.; 15 min) and further extracted with ethanol:water (1:1, by volume; ca 30 mL). Aliquots of each water sample and sediment extract were submitted to liquid scintillation counting. The radioactive content of the residue was determined following combustion.

In addition, non-extractable residues from Day 30 onwards were Soxhlet extracted with ethanol for 24 h following the two initial extractions with ethanol:water. The amount of radioactivity bound to the residue was calculated by difference.

Following sampling, the incubation units were soaked in methanol to recover any residual radioactivity. Aliquots of each apparatus wash were submitted to liquid scintillation counting to quantify the amount of radioactivity present.

Surface water samples and concentrated sediment extracts were analysed by TLC and HPLC. Radioactivity was quantified using a liquid scintillation analyser.

□ Findings

Total Viable Bacteria and Anaerobicity Measurement: From the total viable bacteria estimations, there appeared to be a number of aerobic bacteria and bacterial spores present in the system. However, measurement of the redox potential of the system confirmed that reducing conditions were present throughout the incubation period. Hence, in the absence of oxygen, the aerobic microflora were either inactive or existing as facultative anaerobic bacteria and spores, thus ensuring that the anaerobic degradation of ^{14}C -amitrole could be studied.

Sterility Test: Sterility testing at 30 days, 13 weeks and 26 weeks post-application was performed qualitatively using nutrient broth. Visual assessment of the sterility samples indicated that limited microbial activity was evident. In order to determine whether this was significant, quantitative plate counting techniques were used at 52 weeks. These samples were confirmed as being sterile. As degradation of ^{14}C -amitrole was greater in the 52 week samples compared with the earlier samples, it is likely that although some microbial activity was evident at 30 days, 13 weeks and 26 weeks, this was limited and not sufficient to affect the extent of degradation of ^{14}C -amitrole under anaerobic conditions.

Results are presented in Table 8.4.3-10, Table 8.4.3-12 and Table 8.4.3-14 for viable units at 22°C, in Table 8.4.3-11, Table 8.4.3-13 and Table 8.4.3-15 for viable units at 7°C, and in Table 8.4.3-16, Table 8.4.3-17 and Table 8.4.3-18 for sterile units at 22°C. Overall recoveries of applied radioactivity ranged from a mean of ca 96% to 105%. The recovery of radioactivity from the volatile traps, as $^{14}\text{CO}_2$ and organic volatiles, was very low throughout the incubation period under both sets of incubation conditions, accounting for < ca 1% of the applied radioactivity. The amount of radioactivity associated with the surface water incubated at both temperatures decreased as the incubation progressed, accounting for ca 74% of the applied radioactivity at 52 weeks. Sediment extractable radioactivity remained relatively constant throughout the incubation period, accounting for up to ca 20% at 52 weeks. Bound residues were low (ca 5% at 52 weeks) under both sets of incubation conditions. Negligible differences were observed in the distribution of radioactivity in sterile samples, incubated at 22°C.

Degradate profiling using thin layer chromatography (TLC) indicated that [^{14}C]-amitrole was the major component present in surface waters and sediment extracts throughout the study, accounting for ca 84-87% of the applied radioactivity at 52 weeks in viable samples (ca 71% in sterile samples). A minor polar degradation product, which demonstrated negligible mobility on the TLC plate, was detected in both sediment and water from 26 weeks onwards (accounting for ca 4% in total at study termination). HPLC analysis indicated that this unidentified component may be 2 separate components.

Table 8.4.3-10: Percentage recovery of applied radioactivity (% AR) – Group A – 22°C (mean of replicates)

Sampling time	0 h	1 d	3 d	7 d	10 d	14 d	21 d	30 d	8 w	13 w	26 w	39 w	52 w
Sediment extract	1.51	5.00	7.94	10.28	10.66	10.80	11.58	9.90	9.77	10.43	10.68	13.35	13.45
Associated water	101.16	93.91	87.42	84.74	82.89	81.70	80.10	80.89	77.77	79.15	78.81	74.38	74.18
Organic volatiles	-	0.00	0.00	0.01	0.02	0.02	0.05	0.07	0.07	0.09	0.13	0.10	0.06
CO ₂	-	0.00	0.05	0.32	0.30	0.38	0.29	0.54	0.70	0.78	0.83	0.93	0.95
NER	0.76	2.81	4.58	5.72	6.50	6.09	9.60	9.63	8.83	8.11	10.38	11.66	9.63
Ethanol soxhlet extract	-	-	-	-	-	-	-	3.81	4.33	4.08	4.08	5.69	4.85
Bound residue	-	-	-	-	-	-	-	5.82	4.50	4.04	6.31	5.97	4.78
Apparatus wash	0.15	0.05	0.10	0.23	0.10	0.11	0.09	0.13	0.13	0.09	0.15	0.13	0.58
Total recovery	103.58	101.76	100.08	101.29	100.46	99.09	101.70	101.15	97.26	98.64	100.97	100.54	98.84

Table 8.4.3-11: Percentage recovery of applied radioactivity (% AR) – Group D – 7°C

Sampling time	0 h	1 d	3 d	7 d	10 d	14 d	21 d	30 d	8 w	13 w	26 w	39 w	52 w
Sediment extract	0.46	5.64	8.10	12.54	10.67	11.97	12.14	11.17	11.86	11.23	11.54	15.10	14.50
Associated water	102.01	93.23	87.88	81.99	81.25	81.39	78.12	74.39	76.91	74.95	76.99	72.49	74.40
Organic volatiles	-	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.01
CO ₂	-	0.00	0.00	0.05	0.07	0.09	0.16	0.34	0.60	0.79	1.01	1.05	1.09
NER	0.28	2.81	4.64	5.92	6.71	7.00	10.10	9.83	10.06	8.57	8.89	16.26	9.43
Ethanol soxhlet extract	-	-	-	-	-	-	-	4.89	4.90	5.21	4.37	7.83	4.86
Bound residue	-	-	-	-	-	-	-	4.94	5.16	3.36	4.52	8.43	4.57
Apparatus wash	0.04	0.06	0.33	0.26	0.15	0.10	0.08	0.10	0.17	0.25	0.30	0.16	0.63
Total recovery	102.79	101.74	100.95	100.76	98.85	100.55	100.60	95.83	99.60	95.79	98.73	105.06	100.06

Table 8.4.3-12: TLC characterisation of radioactivity (% AR) – Group A – 22°C (mean of replicates)

Sampling time	0 h	1 d	3 d	7 d	10 d	14 d	21 d	30 d	8 w	13 w	26 w	39 w	52 w
Water	101.16	93.91	87.42	84.74	82.89	81.70	80.10	80.89	77.77	79.15	78.81	74.38	74.18
Amitrole	98.24	80.78	86.13	83.34	80.83	80.60	78.39	79.40	75.79	77.12	76.73	70.18	66.99
Origin	-	-	-	-	-	-	-	-	-	-	-	2.15	3.26
Remaining**	2.92	13.13	1.29	1.4	2.06	1.1	1.71	1.49	1.98	2.03	2.08	2.05	3.93
Sediment***	1.51	5.00	7.94	10.28	10.66	10.80	11.58	9.90 (3.81)	14.10	14.50	14.75	19.04	18.30
Amitrole	-	4.86	7.78	10.06	10.46	10.54	11.24	9.64 (3.74)*	13.84	13.65	13.59	17.96	17.00
Origin	-	-	-	-	-	-	-	-	-	-	0.78	0.49	0.70
Remaining**	1.51	0.14	0.16	0.22	0.2	0.26	0.34	0.26	0.26	0.85	0.38	0.59	0.6
Total													
Amitrole	98.24	95.64	93.91	93.40	91.29	91.14	89.63	92.77	89.63	90.77	90.32	88.13	83.99
Origin	-	-	-	-	-	-	-	-	-	-	0.78	2.64	3.96

* Value in brackets: determined in the 30 days soxhlet extract

** Calculated by RMS

*** Values reported in sediment from 8 to 52 weeks include Sediment extract + ethanol soxhlet extract

Table 8.4.3-13: TLC characterisation of radioactivity (% AR) – Group D – 7°C

Sampling time	0 h	1 d	3 d	7 d	10 d	14 d	21 d	30 d	8 w	13 w	26 w	39 w	52 w
Water	102.01	93.23	87.88	81.99	81.25	81.39	78.12	74.39	76.91	74.95	76.99	72.49	74.40
Amitrole	98.99	90.77	86.67	80.22	79.18	79.18	76.32	72.85	74.74	73.71	74.61	71.17	68.61
Remaining**	3.02	2.46	1.21	1.77	2.07	2.21	1.8	1.54	2.17	1.24	2.38	1.32	5.79
Sediment***	0.46	5.64	8.10	12.54	10.67	11.97	12.14	11.17 (4.89)**	16.76	16.44	15.91	22.93	19.36
Amitrole	-	5.49	7.88	12.20	10.47	11.46	11.86	10.88 (4.75)**	16.44	15.51	14.76	22.11	18.14
Remaining**	0.46	0.15	0.22	0.34	0.2	0.51	0.28	0.29	0.32	0.93	1.15	0.82	1.22
Total													
Amitrole	98.99	96.26	94.55	92.42	89.65	90.64	88.18	88.48	91.18	89.22	89.37	93.28	86.75

* Value in brackets: determined in the 30 days soxhlet extract

** Calculated by RMS

*** Values reported in sediment from 8 to 52 weeks include Sediment extract + ethanol soxhlet extract

Table 8.4.3-14: HPLC characterisation of radioactivity (% AR) – Group A – 22°C (mean of replicates)

Sampling time	0 h	1 d	3 d	7 d	10 d	14 d	21 d	30 d	8 w	13 w	26 w	39 w	52 w
Water	101.16	93.91	87.42	84.74	82.89	81.70	80.10	80.89	77.77	79.15	78.81	74.38	74.18
Amitrole	101.16	93.91	87.42	84.74	82.89	81.70	80.10	80.89	77.77	79.15	70.06	62.65	67.48
Unknown A	-	-	-	-	-	-	-	-	-	-	1.33	6.79	1.12
Unknown B	-	-	-	-	-	-	-	-	-	-	1.69	-	-
Remaining*	0	0	0	0	0	0	0	0	0	0	5.73	4.94	5.58
Sediment**	1.51	5.00	7.94	10.28	10.66	10.80	11.58	13.71	14.10	14.50	14.75	19.04	18.30
Amitrole	-	5.00	7.94	10.28	10.66	10.80	11.58	13.71	14.10	14.50	13.38	17.78	17.16
Unknown A	-	-	-	-	-	-	-	-	-	-	0.25	0.33	0.18
Unknown B	-	-	-	-	-	-	-	-	-	-	-	-	-
Remaining*	1.51	0	0	0	0	0	0	0	0	0	1.12	0.93	0.96
Total													
Amitrole	101.16	98.91	95.36	95.02	93.55	92.50	91.58	94.60	91.87	93.65	83.44	80.42	84.64
Unknown A	-	-	-	-	-	-	-	-	-	-	1.58	7.12	1.30
Unknown B	-	-	-	-	-	-	-	-	-	-	1.69	-	-

* Calculated by RMS

** Values reported in sediment from 30 days to 52 weeks include Sediment extract + ethanol soxhlet extract

Table 8.4.3-15: HPLC characterisation of radioactivity (% AR) – Group D – 7°C

Sampling time	0 h	1 d	3 d	7 d	10 d	14 d	21 d	30 d	8 w	13 w	26 w	39 w	52 w
Water	102.01	93.23	87.88	81.99	81.25	81.39	78.12	74.39	76.91	74.95	76.99	72.49	74.40
Amitrole	102.01	93.23	87.88	81.99	81.25	81.39	78.12	74.39	76.91	74.95	70.19	59.47	58.06
Remaining*	0	0	0	0	0	0	0	0	0	0	6.8	13.02	16.34
Sediment**	0.46	5.64	8.10	12.54	10.67	11.97	12.14	16.06	16.76	16.44	15.91	22.93	19.36
Amitrole	-	5.64	8.10	12.54	10.67	11.97	12.14	16.06	16.76	16.44	14.35	20.83	17.85
Remaining*	0.46	0	0	0	0	0	0	0	0	0	1.56	2.1	1.51
Total													
Amitrole	102.01	98.87	95.98	94.53	91.92	93.36	90.26	90.45	93.67	91.39	84.54	80.30	75.91

* Calculated by RMS

** Values reported in sediment from 30 days to 52 weeks include Sediment extract + ethanol soxhlet extract

Table 8.4.3-16: Percentage recovery of applied radioactivity (% AR) – Group C (sterile) – 22°C (mean of replicates)

Sampling time	30 d	13 w	26 w	52 w
Sediment extract	9.67	9.08	9.57	10.14
Associated water	82.11	81.59	81.27	78.24
Organic volatiles	0.00	0.00	0.01	0.01
CO ₂	0.00	0.03	0.04	0.08
NER	8.53	9.24	10.13	10.16
Ethanol soxhlet extract	4.00	3.60	3.75	4.25
Bound residue	4.54	5.64	6.38	5.91
Apparatus wash	0.15	0.09	0.13	0.28
Total recovery	100.45	100.02	101.13	98.89

Table 8.4.3-17: TLC characterisation of radioactivity (% AR) – Group C (sterile) – 22°C (mean of replicates)

Sampling time	30 d	13 w	26 w	52 w
Water	82.11	81.59	81.27	78.24
Amitrole	77.60	74.18	69.24	58.23
Origin	2.65	2.49	5.87	11.78
Remaining**	1.86	4.92	6.16	8.23
Sediment***	9.67 (4.00)*	12.68	13.32	14.38
Amitrole	9.38 (3.87)*	11.25	12.11	12.48
Origin	-	0.63	0.92	1.16
Remaining**	0.29	0.8	0.29	0.74
Total				
Amitrole	90.84	85.43	81.35	70.70
Origin	2.65	3.12	6.78	12.94

* Value in brackets: determined in the 30 days soxhlet extract

** Calculated by RMS

*** Values reported in sediment from 13 to 52 weeks include Sediment extract + ethanol soxhlet extract

Table 8.4.3-18: HPLC characterisation of radioactivity (% AR) – Group C (sterile) – 22°C (mean of replicates)

Sampling time	30 d	13 w	26 w	52 w
Water	82.11	81.59	81.27	78.24
Amitrole	82.11	76.01	67.06	64.02
Unknown A	-	5.58	2.81	7.19
Unknown B	-	-	4.54	-
Remaining*	0	0	6.86	7.03
Sediment**	13.67	12.68	13.32	14.38
Amitrole	13.67	12.68	11.69	13.28
Unknown A	-	-	0.22	0.15
Unknown B	-	-	0.30	-
Remaining*	0	0	1.11	0.95
Total				
Amitrole	95.77	88.69	78.75	77.30
Unknown A		5.58	3.03	7.34
Unknown B		-	4.84	-

* Calculated by RMS

** Values reported in sediment from 30 days to 52 weeks include Sediment extract + ethanol soxhlet extract

❑ Conclusion

In conclusion, [¹⁴C]-amitrole degrades very slowly under anaerobic conditions, independent of temperature and biological activity. The half-life could not be calculated because of limited degradation, but it exceeds one year.

❑ Comments from RMS

The study is considered acceptable. Although it is noted that in the TLC characterisation of radioactivity (Table 8.4.3-12, Table 8.4.3-12) 13% AR remained unidentified at day 1 in water, the analysis by HPLC showed that the overall radioactivity corresponds to amitrole. The radioactivity defined as “origin” by TLC analysis was also analysed by HPLC, it was found that this unidentified component may be 2 separate components (unknown A and B). These components are not major.

In the experiment performed at 7°C, a part of radioactivity >10% remained unidentified at 39 and 52 weeks (Table 8.4.3-15). It is expected that it corresponds to unknown A and unknown B quantified in the experiment at 20°C, since the way of degradation seems to be very similar at both temperatures.

See also next study for the identification of unknown A.

Williams, S.G.P., McGuire, G.M., 1997 – The identification of a major unknown radioactive component in a surface water sample treated with 14C-amitrole. Inveresk Research International report n°362256. Report amendment 1 to 382817.

❑ **Guidelines:** not relevant

❑ **GLP:** Yes

❑ **Deviations:** None identified

❑ **Acceptability:** Yes

❑ Method

Because a major radioactive component could not be identified in the above-summarized study, further investigations were conducted on this unknown radioactive component.

Additional analysis was performed by liquid chromatography-mass spectrometry and liquid chromatography-tandem mass spectrometry on a sample from incubation unit 40 (week 52) from incubation Group C (sterile). In this sample, the unknown component (unknown A) was observed at ca 11% AR (TLC analysis).

❑ Findings

The major unknown radioactive component in surface water treated with [14C]-amitrole was postulated as being 3-imino-1,2,4-triazole.

The structure was based on the mass spectrum of the component with comparison to that of amitrole reference standard. Amitrole exhibited a spectrum, which was characterized by ions at m/z 85 (MH⁺), 126 (MH⁺ + CH₃CN) and 167 (MH⁺ + 2CH₃CN). The unknown radioactive component exhibited a spectrum, which was characterized by an ion at m/z 83 (MH⁺). This was observed to be a discrete component eluting just before the amitrole peak. No reference standard was supplied to confirm the observed spectrum and retention time of the unknown component.

The daughter ion spectrum of amitrole exhibited the ions at m/z 43 and 58. The daughter ion spectrum of the component with a postulated MH⁺ ion at m/z 83 exhibited ions at m/z 42 and 55. The daughter ions of this component are consistent with them being formed from a dehydrogenated degradation product of amitrole.

Formation of the degradation product would be via a dehydrogenation pathway.

❑ Conclusion

The identity of the major degradation product of amitrole in surface water from an aquatic anaerobic degradation study has been postulated as 3-imino-1,2,4-triazole on the basis of full scan and daughter ion mass spectra. Formation of this product would be *via* a dehydrogenation process.

❑ Comments from RMS

The study is considered acceptable.

B.8.4.4. Summary of degradation pathways and rates of amitrole in water

No new study on the fate and behavior of Amitrole in water was provided, except a water/sediment study under anaerobic conditions. Amitrole is hydrolytically stable at 25°C and pH 5, 7 and 9 and at 90°C and pH 4, 7 and 9. Amitrole is photolytically stable at 25°C and pH 5, 7 and 9. It shows no light absorption above 290 nm. Amitrole is not readily biodegradable.

In dark aerobic water/sediment systems, Amitrole is slowly degraded in total system: 41.3-46.9% AR remain as amitrole after 91 days. In the water phase, it still represents 32.8-43.7% AR at the end of incubation (91 days). Adsorption on sediment is low (maximum 5.9-14% AR after 0-7 days). Non extractable residues reach 26.4-40.1% AR after 91 days. Mineralisation represents 10.3-18.7% AR after 91 days. No major metabolites are identified. Minor metabolites are quantified, among which triazole and urea are identified, always below 2.5% AR.

The rates of degradation/dissipation of Amitrole in water/sediment systems were updated according to the guidance document FOCUS Kinetics (2006). In total system, DT₅₀ ranged between 83.6 and 88.7 days (SFO kinetics). Dissipation rates in water ranged between 67.6 and 87.6 days. Dissipation rates in sediment ranged between 116.8 and 124.8 days.

Table 8.4.4-1: DT₅₀ values of amitrole in aerobic water/sediment systems

Parent	Distribution (eg max in water 86.8-87.4 % after 0 d. Max. sed 5.9-14.0 % after 0-7 d)									
Water / sediment system	pH water phase	pH sed (CaCl ₂)	t. °C	DT ₅₀ -DT ₉₀ whole sys.	St. (χ ²)	DissT ₅₀ -DissT ₉₀ water	St. (χ ²)	DissT ₅₀ -DissT ₉₀ sed	St. (χ ²)	Method of calculation
Pond	8.6	6.9	20	88.7-294.5	3.0	87.6-291.1	3.1	116.8-388.2	1.6	SFO
Ditch	8.3	7.4	20	83.6-277.6	5.3	67.6-224.5	9.7	124.8-414.6	5.7	SFO
Geometric mean				86.1-285.9		77.0-255.6		120.7-401.2		

In dark anaerobic water/sediment systems, Amitrole is very slowly degraded: it still represents 91.4-93.7% AR after 91 days (75.9-84.6% AR after 364 days) in total system. Adsorption on sediment is low (maximum 17.8-20.8% AR after 273 days). No major metabolites were identified. Bound residues represent 6.3-8.4% AR after 182-273 days. Mineralisation is negligible.

B.8.5. IMPACT ON WATER TREATMENT PROCEDURE (ANNEX IIIA 9.2.2)

No additional study was submitted, please refer to the DAR.

B.8.6. PREDICTED ENVIRONMENTAL CONCENTRATIONS IN GROUND WATER AND IN SURFACE WATER (PEC_{GW}, PEC_{SW}) (ANNEX IIIA 9.2.1 AND 9.2.3)

B.8.6.1. Predicted environmental concentrations in ground water

B.8.6.1.1. Predicted environmental concentrations of amitrole in ground water

B.8.6.1.1.1. PEC_{gw} for agricultural uses

The following studies were initially submitted by the applicant.

Bertrand, M., 2011a – Predicted environmental concentrations of Amitrole and 1,2,4-triazole in groundwater following applications on orchards and olives using FOCUS PELMO 4.4.3. Document n° NUFGW26102011.

Bertrand, M., 2011b – Predicted environmental concentrations of Amitrole and 1,2,4-triazole in groundwater following applications on vines using FOCUS PELMO 4.4.3. Document n° NUFGW02112011.

These studies were conducted with the previous endpoints of Amitrole, not determined according to the latest guidance documents. In addition, although it is reported in the title that they were conducted with FOCUS PELMO 4.4.3, the previous version 3.3.2 was used, and the Q10 value was not updated according to EFSA and FOCUS recommendations. Finally, some deviations were identified in the input parameters. Therefore, the applicant was asked to provide new PEC_{gw} calculations using the FOCUS crops apples, citrus and vines. These studies are therefore superseded and not summarised.

The following additional studies were provided by the applicant and are summarised below.

Comoretto, L., 2012b – Predicted environmental concentrations (PEC_{gw}) of Amitrole and 1,2,4-triazole in groundwater following spring application on vines, orchards, citrus and olives using PELMO 4.4.3. Document n° NUFGW19072012.

- ❑ **Guidelines:** FOCUS GW (2000)
- ❑ **GLP:** Not relevant
- ❑ **Deviations:** the FOCUS crop and crop interception are not appropriate
- ❑ **Acceptability:** No
- ❑ **Method**

PEC_{gw} for amitrole and 1,2,4-triazole were calculated using the model FOCUS PELMO 4.4.3, for a yearly application of amitrole. The maximum application rate of amitrole is 2977 g/ha. Since it is an herbicide that is not applied on foliage but through soil directed spray under the row of the defended crops, it is considered that 1/3 of the surface is treated. Therefore the application rate was corrected by 1/3. Since amitrole is applied on well developed weeds, the FOCUS crop “grass” was selected, and a crop interception of 90% was used.

It is reported in the study report that PEC_{gw} calculations for 1,2,4-triazole (reaching 9.9% in photodegradation study) were performed as if 1,2,4-triazole was the active ingredient, and so Amitrole and 1,2,4-triazole were simulated in 2 separated runs. However, when checking the input/output files, it appears that only one run was performed, in which amitrole degraded into 1,2,4-triazole.

The application scheme used is presented in the following table. Two application dates were tested: 15 March and 15 October.

Table 8.6.1-1: Application scheme used for amitrole in FOCUS PELMO 4.4.3

Crop	Grass and alfalfa
Application rate (g/ha)	993 (2977 x 1/3)
Number of applications	1
Crop interception	90%
Dose reaching soil (g/ha)	99.3
Application date	15 March 15 October

The following input parameters were used.

Table 8.6.1-2: Input parameters used for Amitrole

Parameter	Amitrole	Remarks
PHYSICO-CHEMICAL PROPERTIES		
Molecular weight [g mol ⁻¹]	84.08	Review Report (2000)
Water solubility [mg L ⁻¹]	0 (20°C) ^a	-
Vapour pressure [Pa] at 20°C	3.3 x 10 ⁻⁵ (20°C) ^a	Review Report (2000)
DEGRADATION IN SOIL		
DT ₅₀ (soil) [d]	23	Laboratory median value, as initially calculated by the applicant (see Table B8.1.2-5)
Temperature correction function Q10	2.58	FOCUS Recommendation
Moisture correction function moisture exponent [-]	0.7	FOCUS Recommendation
SORPTION TO SOIL		
K _{foc} [L kg ⁻¹]	114	New single value from Menerling, 2012
1/n [-]	0.808	New single value from Menerling, 2012
MANAGEMENT RELATED PARAMETERS		
Crop uptake factor [-]	0.5	Systemic substance

^a RMS notes that since solubility and vapour pressure were set in the model for 1 temperature only, the Henry's law constant was set to 0 by default. Indeed, the new PELMO version requires values at 2 different temperatures.

Table 8.6.1-3: Input parameters used for 1,2,4-triazole

Parameter	1,2,4-triazole	Remarks
PHYSICO-CHEMICAL PROPERTIES		
Molecular weight [g mol ⁻¹]	69.1	EU agreed endpoints
Water solubility [mg L ⁻¹]	Not needed	-
Vapour pressure [Pa] at 20°C	Not needed	-
DEGRADATION IN SOIL		
DT ₅₀ (soil) [d]	60.5	Mean value from the slow phases of DFOP field normalised DT50
Maximum occurrence observed in soil (%)	8.7	A value of 9.9% is reported in the study report, but 8.7% was used in the input files
Temperature correction function Q10	2.58	FOCUS Recommendation
Moisture correction function moisture exponent [-]	0.7	FOCUS Recommendation
SORPTION TO SOIL		
K _{foc} [L kg ⁻¹]	89	EU agreed endpoints
1/n [-]	0.92	EU agreed endpoints
MANAGEMENT RELATED PARAMETERS		
Crop uptake factor [-]	0	Conservative value

□ Findings

Results are reported in the following table. The concentrations of Amitrole and 1,2,4-triazole are below the trigger value of 0.1 µg/L for all scenarios.

Table 8.6.1-4: PEC_{gw} for Amitrole and 1,2,4-triazole in FOCUS PELMO 4.4.3

FOCUS Scenario	PEC _{gw} [µg a.s./L] (80 th percentile at 1 m depth)			
	Amitrole		1,2,4-triazole	
Application	15 March	15 October	15 March	15 October
Châteaudun	<0.001	<0.001	0.049	0.023
Hamburg	<0.001	<0.001	0.041	0.054
Jokioinen	<0.001	<0.001	0.023	0.029
Kremsmünster	<0.001	<0.001	0.033	0.037
Okehampton	<0.001	<0.001	0.050	0.064
Piacenza	<0.001	<0.001	0.056	0.073
Porto	<0.001	<0.001	0.030	0.055
Sevilla	<0.001	<0.001	0.004	0.005
Thiva	<0.001	<0.001	0.013	0.019

❑ Comments from RMS

The study is not considered acceptable. First, calculations were performed for the FOCUS crop “grass” whereas the crops apples, vines and citrus should have been used: indeed, although amitrole is applied on weeds, the proposed use should be used in the simulations so that the specificities related to each crop are taken into account in the simulations. In addition, the use of a crop interception of 90% is not considered acceptable. RMS agrees that amitrole will be applied on weeds. However, an interception of 90% corresponds to an established turf. This would not be conservative enough. The standard practice for herbicide applied on vines and orchards is to use a crop interception of 0% since the herbicide is not applied on the crop.

For Amitrole, the updated soil DT₅₀ to be used is the geometric mean of 7.4 days. In addition, the applicant only used the new single K_{foc} and 1/n derived from the new study of Menerling (2012), whereas this value should have been pooled with the other validated K_{foc} and 1/n values.

For metabolite 1,2,4-triazole, the applicant used the maximum observed occurrence as formation fraction. Although it is not the standard practice, RMS considers that it may be accepted in this case since 1,2,4-triazole is only formed by photodegradation (since amitrole is rapidly degraded by soil micro-organisms, it is expected that the maximum occurrence of 9.9% will not be reached under field conditions. Therefore, the maximum occurrence may be used as formation fraction in this case).

The applicant provided 2 additional studies. The first one is a statement on the formation fraction of 1,2,4-triazole to be used in PEC_{gw} modelling. The second presents new PEC_{gw} calculations (with 40% interception).

Comoretto, L., 2012c – Statement on the percentage of formation of 1,2,4-triazole used for the modelling GW. Study No.: NUFamitrole31082012.

❑ Summary

According to Hawkins (1982a), whatever the ¹⁴C position, aminotriazole was highly mineralized when applied at 1 ppm to soil A or B. ¹⁴CO₂ was mainly released for the first week. After 64 days, it was 41-77%, extracts were <2% and bound residues 18-58% - recovery was 92-100%. Under any non sterile condition, extracts rapidly decreased from 87% to low levels (<5% after 2 weeks) and unextracted residues rapidly peaked (20-40% in soil A and 50% in soil B). The conclusion of the study was that aminotriazole is rapidly degraded in soil under aerobic condition (<5% remaining after 2 weeks). It is highly mineralized (40-80%) by microorganisms and acceptable amounts of bound residues are formed (<60%). **So, only 50% of amitrole is still available for any degradation process after the first week and after 2 weeks, quantity of amitrole is <5%.**

According to Scholz (1988), Aminotriazole was rapidly mineralized (¹⁴CO₂ represents 13.8-25.8% since the 1st day of degradation). At least two minor unidentified polar metabolites were also detected. About half of bound residues were identified as aminotriazole. **So, amitrole is degraded rapidly by microbial activity and it leads to no formation to 1,2,4 triazole.**

In Huhtanen (1985) (photodegradation study 1), recovery was 74-86% and $^{14}\text{CO}_2$ was evolved. Aminotriazole degraded in dry soil in the dark due to only microbial activity even if microbial activity in the dark is decreased. The degradation when exposed under light conditions increased due to the augmentation of the microbial activity. Unidentified metabolites and bound residues could reach 34 and 10% respectively. In Das (1990) (photodegradation study 2), recovery was 92-100%, extractable radioactivity was 88-99% and bound residues were <9%. Aminotriazole was not significantly degraded in darkness because of sterile condition. In light condition, always in sterile conditions, the degradation increase but not represent a major way of degradation, the DT50 of the amitrole is still high. 1,2,4-triazole was the only detected degradation product (<10%). It represents a minor non transient metabolite.

So, according to Das 1990, 1,2,4 triazole is formed at 9.9% after 30 days. But this formation was observed only in sterile condition under irradiated condition. In the environment, soils are not sterile, soils are the media where the microbial activity is high so the formation of 1,2,4 triazole is unlikely to occur even more if we compare the kinetic of mineralization and the kinetic of formation of 1,2,4 triazole. Moreover, since the first days of the application of amitrole 50% is mineralized so we can divide the % of formation of triazole by two according this result.

Finally, according to Kampe (1987), Aminotriazole is mobile in soil immediately after treatment but mobility significantly changes with soil type and sorption capacity. More than 50%, is located in the first centimeters of soils and can't be exposed to light for degradation.

After considering all this argument, we can conclude that, the formation of 1,2,4 triazole seems not possible or if it is formed, it is formed around 2.5%. (9.9% of formation of triazole after 30 days, but 50% of amitrole is mineralized after only one week and 50% is in the soil column and not available for photolysis degradation after 30 days). So it would be relevant for the calculation of PEC_{gw} to take 2.5%.

❑ Comments from RMS

RMS does not fully agree with the applicant. It is agreed that microbial degradation and photodegradation in soil will be concomitant processes. Since amitrole is rapidly degraded by micro-organisms, the maximum occurrence of 1,2,4-triazole in field is not expected to reach the value of 9.9% obtained in the photodegradation study. In addition, as already mentioned by RMS, photodegradation of amitrole is not expected to be a significant route of degradation of amitrole for the sustained uses. However, the use of a ffm of 2.5% cannot be accepted, since it only relies on assumptions which are not corroborated by calculations.

It is also noted that the applicant mentioned that 1,2,4-triazole reached 9.9% in a sterile soil in the photodegradation study of Das (1990). RMS checked the study and did not find an indication that the soil had been sterilised.

Comoretto, L., 2012d – Predicted environmental concentrations (PEC_{gw}) of Amitrole and 1,2,4-triazole in groundwater following spring application on vines, orchards, citrus and olives using PELMO 4.4.3. Document n° NUFGW31082012.

❑ **Guidelines:** FOCUS GW (2000)

❑ **GLP:** Not relevant

❑ **Deviations:** the FOCUS crop and crop interception are not appropriate

❑ **Acceptability:** No

❑ **Method**

PEC_{gw} for amitrole and 1,2,4-triazole were calculated using the model FOCUS PELMO 4.4.3, for a yearly application of amitrole. The maximum application rate of amitrole is 2977 g/ha. Since it is an herbicide that is not applied on foliage but through soil directed spray under the row of the defended crops, it is considered that 1/3 of the surface is treated. Therefore the application rate was corrected by 1/3. Since amitrole is applied on well developed weeds, the FOCUS crop "grass" was selected, and a crop interception of 40% was used.

Based on the statement summarised above, a formation fraction for 1,2,4-triazole of 2.5% was used.

The application scheme used is presented in the following table. Two application dates were tested: 15 March and 15 October.

Table 8.6.1-5: Application scheme used for amitrole in FOCUS PELMO 4.4.3

Crop	Grass and alfalfa
Application rate (g/ha)	993 (2977 x 1/3)
Number of applications	1
Crop interception	40%
Dose reaching soil (g/ha)	595.4
Application date	15 March 15 October

The following input parameters were used.

Table 8.6.1-6: Input parameters used for Amitrole

Parameter	Amitrole	Remarks
PHYSICO-CHEMICAL PROPERTIES		
Molecular weight [g mol ⁻¹]	84.08	Review Report (2000)
Water solubility [mg L ⁻¹]	0 (20°C)	-
Vapour pressure [Pa] at 20°C	3.3 x 10 ⁻⁵ (20°C)	Review Report (2000)
DEGRADATION IN SOIL		
DT ₅₀ (soil) [d]	24,6*	Reported as laboratory median value, as initially calculated by the applicant (see Table 8.1.2-5)
Temperature correction function Q10	2.58	FOCUS Recommendation
Moisture correction function moisture exponent [-]	0.7	FOCUS Recommendation
SORPTION TO SOIL		
K _{foc} [L kg ⁻¹]	114	New single value from Menerling, 2012
1/n [-]	0.808	New single value from Menerling, 2012
MANAGEMENT RELATED PARAMETERS		
Crop uptake factor [-]	0.5	Systemic substance

* A value of 23 days is mentioned in the report but when checking the input/output files, it appeared that a value of 24.6 days was used.

^a RMS notes that since solubility and vapour pressure were set in the model for 1 temperature only, the Henry's law constant was set to 0 by default. Indeed, the new PELMO version requires values at 2 different temperatures.

Table 8.6.1-7: Input parameters used for 1,2,4-triazole

Parameter	1,2,4-triazole	Remarks
PHYSICO-CHEMICAL PROPERTIES		
Molecular weight [g mol ⁻¹]	69.1	EU agreed endpoints
Water solubility [mg L ⁻¹]	Not needed	-
Vapour pressure [Pa] at 20°C	Not needed	-
DEGRADATION IN SOIL		
DT ₅₀ (soil) [d]	60.5	Mean value from the slow phases of DFOP field normalised DT50
Maximum occurrence observed in soil (%)	2.5	According to the statement from Comoretto, 2012
Temperature correction function Q10	2.58	FOCUS Recommendation
Moisture correction function moisture exponent [-]	0.7	FOCUS Recommendation
SORPTION TO SOIL		
K _{foc} [L kg ⁻¹]	89	EU agreed endpoints
1/n [-]	0.92	EU agreed endpoints
MANAGEMENT RELATED PARAMETERS		
Crop uptake factor [-]	0	Conservative value

Findings

Results are reported in the following table. The concentrations of Amitrole and 1,2,4-triazole are below the trigger value of 0.1 µg/L for all scenarios.

Table 8.6.1-8: PECgw for Amitrole and 1,2,4-triazole in FOCUS PELMO 4.4.3

FOCUS Scenario	PECgw [µg a.s./L] (80 th percentile at 1 m depth)			
	Amitrole		1,2,4-triazole	
Application	15 March	15 October	15 March	15 October
Châteaudun	<0.001	<0.001	0.036	0.045
Hamburg	<0.001	<0.001	0.075	0.106
Jokioinen	<0.001	<0.001	0.044	0.059
Kremsmünster	<0.001	<0.001	0.061	0.071
Okehampton	<0.001	<0.001	0.092	0.123
Piacenza	0.001	0.004	0.103	0.134
Porto	<0.001	0.001	0.055	0.105
Sevilla	<0.001	<0.001	0.007	0.010
Thiva	<0.001	<0.001	0.024	0.041

Comments from RMS

The study is not considered acceptable. Calculations were performed for the FOCUS crop “grass” whereas the crops apples, vines and citrus should have been used: indeed, although amitrole is applied on weeds, the proposed use should be used in the simulations so that the specificities related to each crop are taken into account in the simulations. In addition, the use of a crop interception of 40% is still not considered acceptable. As already explained, the standard practice for herbicide applied on vines and orchards is to use a crop interception of 0%. In addition, as explained in the comments of the statement presented above, the formation fraction of 2.5% cannot be accepted.

Consequently, RMS performed new PECgw calculations. Although RMS considers that 1,2,4-triazole will not be formed in significant amounts for the sustained uses and might not need to be included in the risk assessment

(see B.8.1.3), PEC_{gw} are calculated for this metabolite for information since the metabolite was initially included in the risk assessment by the applicant. Details of the simulations are reported below.

The model FOCUS PELMO 4.4.3 was used. An application rate of 2977 g/ha corrected by 1/3 was considered, to take into account the banded application. No crop interception was considered. As proposed by the applicant, calculations were performed on 15 March and 15 October. The FOCUS crops apples, vines and citrus (covering also olives) were used. Since 1,2,4-triazole is formed by photodegradation and no standard formation fraction is available, calculations were performed using a pseudo-application: the application rate of amitrole (corrected by 1/3 for banded application) was corrected by maximum occurrence of 9.9% and molar ratio.

The input parameters used are reported in Table 8.6.1-10 and Table 8.6.1-11. Parameters not reported were left to their default FOCUS values. It is noted that for 1,2,4-triazole, the new agreed endpoints define a DFOP DT50 for use in modelling. This was implemented in FOCUS model as recommended in the FOCUS Kinetic guidance document: 2 simulations were performed for the metabolite. The first-one was conducted for the fast phase, using a DT50 of 1.68 days and correcting the application rate by $g=0.489$. The second one was conducted for the slow phase using a DT50 of 60.5 days and correcting the application rate by $1-g=0.511$. The concentrations are then summed to get the total concentration. Since $1/n$ for 1,2,4-triazole differs from 1, a conservative estimate was made by doubling the application rate and then dividing the final answer by 2.

The application rates used for amitrole and 1,2,4-triazole are reported in the following table.

Table 8.6.1-9: Dose used in PELMO for Amitrole and 1,2,4-triazole (RMS)

Amitrole	
Dose applied (g/ha)	2977
Correction for banded application	1/3
Correction for crop interception (%)	0
Dose reaching soil (g/ha)	992
1,2,4-triazole	
Dose reaching soil (g/ha) (pseudo-application)	$992 \times 0.099 \times 69.1 / 84.08 = 80.7$
Correction for $1/n \neq 1$	$80.7 \times 2 = 161.4$
Dose reaching soil (g/ha) for fast-phase	$161.4 \times 0.489 = 78.9$
Dose reaching soil (g/ha) for slow-phase	$161.4 \times 0.511 = 82.5$

Table 8.6.1-10: Input parameters used for Amitrole (RMS)

Parameter	Amitrole	Remarks
PHYSICO-CHEMICAL PROPERTIES		
Molecular weight [g mol ⁻¹]	84.08	Review Report (2000)
Water solubility [mg L ⁻¹]	264 000 (20°C) 528 000 (30°C)	Review Report (2000) Calculated ^a
Vapour pressure [Pa] at 20°C	3.3×10^{-5} (20°C) 1.32×10^{-4} (30°C)	Review Report (2000) Calculated ^a
DEGRADATION IN SOIL		
DT ₅₀ (soil) [d]	7.4	Geometric mean
Temperature correction function Q10	2.58	FOCUS Recommendation
Moisture correction function moisture exponent [-]	0.7	FOCUS Recommendation
SORPTION TO SOIL		
K _{foc} [L kg ⁻¹]	111	Median (n=9)
1/n [-]	0.81	Median (n=9)
MANAGEMENT RELATED PARAMETERS		
Crop uptake factor [-]	0.5	Systemic substance

^a Values of solubility and vapour pressure at 2 different temperatures are now required in PELMO 4.4.3. Values at one temperature only are reported in the Review Report. The FOCUS Helpdesk recommended to use a temperature 10°C higher, to enter the double solubility and to enter a four times higher vapour pressure.

Table 8.6.1-11: Input parameters used for 1,2,4-triazole (RMS)

Parameter	1,2,4-triazole	Remarks
PHYSICO-CHEMICAL PROPERTIES		
Molecular weight [g mol ⁻¹]	69.1	EU agreed endpoints
Water solubility [mg L ⁻¹]	730 000 (20°C) 1 460 000 (30°C)	From EFSA Journal on tebuconazole Calculated ^a
Vapour pressure [Pa] at 20°C	10 ⁻¹⁰ (20°C) 4 x 10 ⁻¹⁰ (30°C)	Considered conservative Calculated ^a
DEGRADATION IN SOIL		
DT ₅₀ (soil) [d]	1.68 for fast phase 60.5 for slow phase g = 0.489	Mean value from field normalised DT50, DFOP kinetic
Temperature correction function Q10	2.58	FOCUS Recommendation
Moisture correction function moisture exponent [-]	0.7	FOCUS Recommendation
SORPTION TO SOIL		
K _{loc} [L kg ⁻¹]	89	EU agreed endpoints
1/n [-]	0.92	EU agreed endpoints
MANAGEMENT RELATED PARAMETERS		
Crop uptake factor [-]	0	Conservative value

^a Values of solubility and vapour pressure at 2 different temperatures are now required in PELMO 4.4.3. Values at one temperature only are reported in the Review Report. The FOCUS Helpdesk recommended to use a temperature 10°C higher, to enter the double solubility and to enter a four times higher vapour pressure.

80th percentiles of mean annual concentrations of Amitrole and 1,2,4-triazole are reported in the following tables. For Amitrole, PEC_{gw} are < 0.001 µg/L for all scenarios and all crops considered. For 1,2,4-triazole, PEC_{gw} exceed 0.1 µg/L for all scenarios and all crops considered.

Table 8.6.1-12: PEC_{gw} for amitrole in FOCUS PELMO 4.4.3 (RMS)

FOCUS Scenario	PEC _{gw} [µg a.s./L] (80 th percentile at 1 m depth)					
	Apples		Vines		Citrus	
Application	15 March	15 October	15 March	15 October	15 March	15 October
Châteaudun	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Hamburg	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Jokioinen	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Kremsmünster	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Okehampton	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Piacenza	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Porto	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Sevilla	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Thiva	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001

Table 8.6.1-13: PEC_{gw} for 1,2,4-triazole in FOCUS PELMO 4.4.3 following application on apples (RMS)

FOCUS Scenario	PEC _{gw} [µg a.s./L] (80 th percentile at 1 m depth)					
Application	15 March			15 October		
	Fast-phase	Slow-phase	Final concentration ^a	Fast-phase	Slow-phase	Final concentration ^a
Châteaudun	<0.001	1.243	0.622	<0.001	1.247	0.624
Hamburg	<0.001	1.005	0.503	<0.001	1.626	0.813
Jokioinen	<0.001	0.509	0.255	<0.001	0.750	0.375
Kremsmünster	<0.001	0.887	0.444	<0.001	1.097	0.549
Okehampton	<0.001	1.212	0.606	<0.001	1.777	0.889
Piacenza	<0.001	1.043	0.522	<0.001	1.398	0.699
Porto	<0.001	0.601	0.301	<0.001	1.265	0.633
Sevilla	<0.001	0.722	0.361	<0.001	0.669	0.335
Thiva	<0.001	0.715	0.358	<0.001	1.059	0.530

^a Final concentration = (Concentration from fast phase + concentration from slow phase) / 2 according to FOCUS KineticTable 8.6.1-14: PEC_{gw} for 1,2,4-triazole in FOCUS PELMO 4.4.3 following application on vines (RMS)

FOCUS Scenario	PEC _{gw} [µg a.s./L] (80 th percentile at 1 m depth)					
Application	15 March			15 October		
	Fast-phase	Slow-phase	Final concentration ^a	Fast-phase	Slow-phase	Final concentration ^a
Châteaudun	<0.001	0.926	0.463	<0.001	1.034	0.517
Hamburg	<0.001	0.858	0.429	<0.001	1.341	0.671
Kremsmünster	<0.001	0.781	0.391	<0.001	0.948	0.474
Piacenza	<0.001	0.837	0.419	<0.001	1.237	0.619
Porto	<0.001	0.524	0.262	<0.001	1.227	0.614
Sevilla	<0.001	0.338	0.169	<0.001	0.335	0.168
Thiva	<0.001	0.367	0.184	<0.001	0.806	0.403

^a Final concentration = (Concentration from fast phase + concentration from slow phase) / 2 according to FOCUS KineticTable 8.6.1-15: PEC_{gw} for 1,2,4-triazole in FOCUS PELMO 4.4.3 following application on citrus (RMS)

FOCUS Scenario	PEC _{gw} [µg a.s./L] (80 th percentile at 1 m depth)					
Application	15 March			15 October		
	Fast-phase	Slow-phase	Final concentration ^a	Fast-phase	Slow-phase	Final concentration ^a
Piacenza	<0.001	0.710	0.355	<0.001	1.215	0.608
Porto	<0.001	0.443	0.222	<0.001	1.109	0.555
Sevilla	<0.001	0.284	0.142	<0.001	0.647	0.324
Thiva	<0.001	0.343	0.172	<0.001	1.093	0.547

^a Final concentration = (Concentration from fast phase + concentration from slow phase) / 2 according to FOCUS Kinetic**RMS conclusion on PEC_{gw}:**

No risk of groundwater contamination by Amitrole is expected (PEC_{gw}<0.001 µg/L). The calculations performed for 1,2,4-triazole (relevant metabolite according to SANCO/221/2000) show that PEC_{gw} exceed 0.1

µg/L for all scenarios and all uses. It is however highlighted that PEC_{gw} for 1,2,4-triazole are expected to be overestimated. As explained under B.8.1.3, according to the sustained GAP, photodegradation is not expected to be a major route of degradation of amitrole in soil and therefore 1,2,4-triazole is not expected to be formed in significant amounts. In addition, photodegradation and microbial degradation will be concomitant and concurrent processes. Therefore, if photodegradation occurs in field, the maximum occurrence reached is expected to be lower than 9.9%. Refined PEC_{gw} shall be submitted by the applicant to show that a safe use can be identified for metabolite 1,2,4-triazole.

Although it is difficult to predict whether 1,2,4-triazole will be formed in significant amount or not according to the proposed GAP, it is noted that even if it is formed in small amount, there is a high risk that it will exceed the drinking water limit because of the high applied dose of the parent.

B.8.6.1.1.2. PEC_{gw} for non crop uses

Three situations have to be considered for non crop uses:

- The application is done on permeable surfaces: in this case, it is considered that the FOCUS models used for agricultural uses can be used. The best way would be to conduct additional simulations on the FOCUS crop “grass” but it is expected that results would be similar to results obtained for agricultural crops: PEC_{gw} for Amitrole would be <0.001 µg/L and PEC_{gw} for 1,2,4-triazole would be > 0.1 µg/L. Additional simulations were therefore not performed by RMS.
- The application is done on impermeable surfaces. It is considered that no exposure of groundwater will occur for applications on impermeable surfaces.
- The application is done on railways. The standard calculations with the FOCUS tools are not appropriate. As far as we know, there is no EU agreed tool for these uses. It is proposed to use the model HardSPEC, used by CRD. The latest version of the model (v. 1.4.2) was used.

Calculations for railways are reported below.

Bertrand, M., 2011c – Predicted environmental concentrations of Amitrole and 1,2,4-triazole in groundwater (PEC_{gw}), surface water (PEC_{sw}) and sediment (PEC_{sed}) following applications on non crops using HardSPEC 1.2. Document n° NUFGW03112011.

Since calculations were performed with “old” endpoints and with an old version of HardSPEC, the applicant was asked to provide new simulations. The study is therefore superseded and not summarised.

The following additional study was provided by the applicant and is summarised below.

Comoretto, L., 2012e – Predicted environmental concentrations of Amitrole in groundwater (PEC_{gw}), surface water (PEC_{sw}) and sediment (PEC_{sed}) following application on non crop using HardSPEC 1.4.2. Document n° NUFHS22072012A.

- ☐ **Guidelines:** not reported
- ☐ **GLP:** Not relevant
- ☐ **Deviations:** Yes, see comments
- ☐ **Acceptability:** Yes
- ☐ **Method**

PEC_{gw} for Amitrole following applications on non crop uses were calculated using the model HardSPEC 1.4.2. The maximum application rate of Amitrole (2977 g/ha) was used for PEC_{gw} calculation.

The following input parameters were used in the calculations.

Table 8.6.1-16: Input parameters used for amitrole in HardSPEC

Herbicide properties	Value	Comment
Herbicide name	amitrole	
% of applied amount impacting as spray drift. Urban & Major road	2.8	Default value
% of domestic scenario areas treated	10	Default value
Measured Kp asphalt (mg m ⁻²)	not known	
Measured Kp concrete (mg m ⁻²)	not known	
soil koc (mL g ⁻¹)	114	Value from Menerling, 2012
solubility (mg L ⁻¹)	264000	Review Report (2000)
Specific Gravity	1.138	Review Report (2000)
DT50 in soil (days)	23	Median
DT50 on hard surfaces (days)	not known	
DT50 in sediment (days)	118*	-
DT50 in water (days)	67*	-
Application amount (g/ha)		
Urban	2977	-
Sub-urban (domestic use)	2977	-
Road	2977	-
Railway	2977	-
Uncertainty factors		
Fraction of 774.7 m ² railway track target area actually sprayed	1	Default value
Run-off attenuation factor applied to leached load from ballast	1	Default value

* Values of 112 and 77 for water and sediment respectively are mentioned in the report, but it was checked in the excel spreadsheets that the values used were 118 and 67 respectively.

□ Findings

Results are reported in the following table.

Table 8.6.1-17: PECgw calculated for amitrole using HardSPEC

Railway over Groundwater			
Average annual concentration at the base of the railway formation (mg / L)			0.64
Exposure at the abstraction well-head	Chalk	Limestone	Sandstone
Maximum concentration in well (µg / L)	0.0835	0.0038	0.0042
Period when plume > 0.1 µg / L in well (days)	0.0	0.0	0.0

It is concluded that the concentrations of Amitrole are below the trigger value of 0.1 µg/L for all PECgw scenarios.

□ RMS comments

Although some slight deviations were identified, the study is considered acceptable:

- The soil DT50 was set to 23 days. This is a conservative value compared to the geometric mean of 7.4 days that would have been used by RMS.
- The Koc was set to 114 mL/g (value from Menerling, 2012), whereas a median value of 111 mL/g would have been used by RMS. This will have no impact on the PECgw values.
- The origin of the DT50 used for water and sediment is not clear but values are not used for PECgw calculations.

B.8.6.1.2. Predicted environmental concentrations of Amitrole metabolites in ground water

Calculations are presented by the applicant for 1,2,4-triazole. It is reminded that RMS considers that this metabolite will not be formed in significant amounts for the sustained uses, and therefore do not need to be included in the risk assessment. However, calculations are presented for information.

B.8.6.1.2.1. PEC_{gw} for agricultural uses

Please refer to B.8.6.1.1.1.

B.8.6.1.2.2. PEC_{gw} for non crop uses

Three situations have to be considered for non crop uses:

- The application is done on permeable surfaces: in this case, it is considered that the FOCUS models used for agricultural uses can be used. The best way would be to conduct additional simulations on the FOCUS crop “grass” but it is expected that results would be similar to results obtained for agricultural crops: PEC_{gw} for Amitrole would be <0.001 µg/L and PEC_{gw} for 1,2,4-triazole would be > 0.1 µg/L. Additional simulations were therefore not performed by RMS.
- The application is done on impermeable surfaces. It is considered that no exposure of groundwater will occur for applications on impermeable surfaces.
- The application is done on railways. The standard calculations with the FOCUS tools are not appropriate. As far as we know, there is no EU agreed tool for these uses. It is proposed to use the model HardSPEC, used by CRD. The latest version of the model (v. 1.4.2) was used.

Calculations for railways are reported below.

Bertrand, M., 2011c – Predicted environmental concentrations of Amitrole and 1,2,4-triazole in groundwater (PEC_{gw}), surface water (PEC_{sw}) and sediment (PEC_{sed}) following applications on non crops using HardSPEC 1.2. Document n° NUFGW03112011.

Since calculations were performed with “old” endpoints and with an old version of HardSPEC, the applicant was asked to provide new simulations. The study is therefore superseded and not summarised.

The following additional study was provided by the applicant and is summarised below.

Comoretto, L., 2012f – Predicted environmental concentrations (PEC) of 1,2,4-triazole in groundwater (PEC_{gw}), surface water (PEC_{sw}) and sediment (PEC_{sed}) following application on non crop using HardSPEC 1.4.2. Document n° NUFHS22072012B.

☐ **Guidelines:** not reported

☐ **GLP:** Not relevant

☐ **Deviations:** none identified

☐ **Acceptability:** Yes

☐ **Method**

PEC_{gw} for 1,2,4-triazole following applications on non crop uses were calculated using the model HardSPEC 1.4.2. The maximum application rate of Amitrole (2977 g/ha) was corrected for the soil maximum occurrence of 1,2,4-triazole (9.9%) and molecular ratio (69.1/84.08), giving an application rate of 242 g/ha of 1,2,4-triazole.

The following input parameters were used in the calculations.

Table 8.6.1-18: Input parameters used for 1,2,4-triazole in HardSPEC

Herbicide properties	Value	Comment
Herbicide name	1,2,4-triazole	
% of applied amount impacting as spray drift. Urban & Major road	2.8	Default value
% of domestic scenario areas treated	10	Default value
Measured Kp asphalt (mg m^{-2})	not known	
Measured Kp concrete (mg m^{-2})	not known	
soil koc (mL g^{-1})	89	Mean K _{oc} (agreed EU endpoints)
solubility (mg L^{-1})	730000	Agreed EU endpoint
Specific Gravity	1.138	The same value as for amitrole was used
DT50 in soil (days)	60.5	Mean value from the slow phases of DFOP, field normalised DT50
DT50 on hard surfaces (days)	not known	
DT50 in sediment (days)	1000	Conservative value
DT50 in water (days)	1000	Conservative value
Application amount (g/ha)		
Urban	242	-
Sub-urban (domestic use)	242	-
Road	242	-
Railway	242	-
Uncertainty factors		
Fraction of 774.7 m ² railway track target area actually sprayed	1	Default value
Run-off attenuation factor applied to leached load from ballast	1	Default value

Findings

Results are reported in the following table.

Table 8.6.1-19: PEC_{gw} calculated for 1,2,4-triazole using HardSPEC

Railway over Groundwater			
Average annual concentration at the base of the railway formation (mg / L)			0.08
Exposure at the abstraction well head	Chalk	Limestone	Sandstone
Maximum concentration in well ($\mu\text{g} / \text{L}$)	0.0657	0.0263	0.0257
Period when plume > 0.1 $\mu\text{g} / \text{L}$ in well (days)	0.0	0.0	0.0

It is concluded that the concentrations of 1,2,4-triazole are below the trigger value of 0.1 $\mu\text{g/L}$ for all PEC_{gw} scenarios.

RMS comments

The proposed calculations are acceptable.

B.8.6.1.1. Summary of PEC_{gw} for Amitrole and its metabolites

PEC_{gw} were calculated for Amitrole and 1,2,4-triazole. For agricultural uses, PEC_{gw} were calculated with the model FOCUS PELMO 4.4.3, for the worst-case application rate of 2977 g/ha, corrected by 1/3 to take into account the banded application, with no interception. PEC_{gw} for Amitrole are < 0.001 $\mu\text{g/L}$ for all scenarios and all uses. For 1,2,4-triazole, PEC_{gw} exceed 0.1 $\mu\text{g/L}$ for all scenarios and all uses. However, it is highlighted that PEC_{gw} for 1,2,4-triazole are expected to be overestimated. As explained under B.8.1.3, according to the

sustained GAP, photodegradation is not expected to be a major route of degradation of amitrole in soil and therefore 1,2,4-triazole is not expected to be formed in significant amounts. In addition, photodegradation and microbial degradation will be concomitant and concurrent processes. Therefore, if photodegradation occurs in field, the maximum occurrence reached is expected to be lower than 9.9%. **Refined PEC_{gw} for metabolite 1,2,4-triazole shall be submitted by the applicant to show that a safe use can be identified.**

No specific calculations were performed for non crop uses on permeable surfaces, however the same conclusions as for agricultural uses are expected. For non crop uses on impermeable surfaces, no risk of groundwater contamination is expected.

For the specific uses on railways, the model HardSPEC v. 1.4.2 was used. PEC_{gw} for Amitrole ranged between 0.0038 to 0.0835 µg/L. PEC_{gw} for 1,2,4-triazole ranged between 0.0257 and 0.0657 µg/L. Therefore, no risk of groundwater contamination is expected.

B.8.6.2. Predicted environmental concentrations in surface water

B.8.6.2.1. Predicted environmental concentrations of amitrole in surface water

B.8.6.2.1.1. PEC_{sw} for agricultural uses

The following studies were initially provided by the applicant.

Bertrand, M., 2011d – Predicted environmental concentrations of Amitrole in surface water and sediment (PEC_{sw} and PEC_{sed}) according to FOCUS surface water scenario following applications on pome and stone fruits. Document n° NUFSW301108.

Bertrand, M., 2011e – Predicted environmental concentrations of Amitrole in surface water and sediment (PEC_{sw} and PEC_{sed}) according to FOCUS surface water scenario following applications on grapes. Document n° NUFSW301108.

These studies were conducted with the “old” endpoints of Amitrole, not determined according to the latest guidance documents. In addition, the values of Q_{10} , activation energy and alpha factor were not updated according to EFSA and FOCUS recommendations.

Crop interception was taken into account in Step 1-4. In Step 3-4, the application rate was divided by 3 to take into account the banded application. RMS agrees that this can be done for drainage and run-off entry routes, but not for drift entries that would be underestimated. Consequently, RMS asked the applicant to provide new calculations with updated endpoints, with a crop interception of 0, considering the full dose for the drift entries and a lower dose (1/3) for the drainage and run-off entries, and correcting the drift entries to take into account that amitrole is applied on the ground and not on foliage (as recommended by FOCUS SW guidance document). The studies of Bertrand 2011d & e are therefore superseded and not summarised.

The following additional studies were provided by the applicant and are summarised below.

Comoretto, L., 2012g – Predicted environmental concentrations (PEC) of Amitrole in surface water and sediment (PEC_{sw} and PEC_{sed}) according to FOCUS surface water scenarios after applications on citrus. Document n° NUFSW22072012A.

Comoretto, L., 2012h – Predicted environmental concentrations (PEC) of Amitrole in surface water and sediment (PEC_{sw} and PEC_{sed}) according to FOCUS surface water scenarios after applications on olives. Document n° NUFSW22072012B.

Comoretto, L., 2012i – Predicted environmental concentrations (PEC) of Amitrole in surface water and sediment (PEC_{sw} and PEC_{sed}) according to FOCUS surface water scenarios after applications on vines. Document n° NUFSW19072012C.

Comoretto, L., 2012j – Predicted environmental concentrations (PEC) of Amitrole in surface water and sediment (PEC_{sw} and PEC_{sed}) according to FOCUS surface water scenarios after applications on orchards. Document n° NUFSW22072012D.

❑ **Guidelines:** FOCUS SW (2001)

❑ **GLP:** Not relevant

❑ **Deviations:** Yes, see comments

❑ **Acceptability:** No

❑ **Method**

PEC_{sw} and PEC_{sd} for amitrole were calculated using the FOCUS tools. FOCUS Step 1-2 version 1.1 was used for vines only. FOCUS Step 3-4 calculations were performed for all crops: citrus, olives, vines and pome/stone fruits with the models FOCUS SWASH 3.1, TOXSWA 3.3.1, MACRO 4.4.2, PRZM 1.1.1 and SWAN 1.1.4.

For Step 1-4, one single application per year was considered. Since amitrole is applied by under the rows only, the application rate was factored by 1/3 for band applications. It is noted in the reports that in Step 3-4, since the application method used was set to airblast, the use of the default scenarios will result in incorrect drift loadings and crop interception.

The application schemes used in FOCUS Step 1-2 and Step 3-4 are presented in the tables below. The application windows used in Step 3-4 are also reported below.

Table 8.6.2-1: Application scheme used for amitrole in FOCUS Step 1-2

Crop	Vines, early & late applications
Application rate (g/ha)	992 (2977 x 1/3)
Number of applications	1
Crop interception	No interception
Region and season of application	North & South Europe – Oct-Feb

Table 8.6.2-2: Application scheme used for amitrole in FOCUS Step 3-4

Crop	Pome/stone fruits (early & late)	Vines (early)	Olives	Citrus
Application rate (g/ha)	992 (2977 x 1/3)	992 (2977 x 1/3)	458 (1375 x 1/3)	992 (2977 x 1/3)
Number of applications	1	1	1	1
Method of application	Airblast CAM 1, DEPI = 0	Airblast CAM 1, DEPI = 0	Airblast CAM 1, DEPI = 0	Airblast CAM 1, DEPI = 0
Crop interception	Calculated by the model	Calculated by the model	Calculated by the model	Calculated by the model

Table 8.6.2-3: Application windows used in SWASH for Step 3-4

Scenario	Pome/stone fruits (early)	Pome/stone fruits (late)	Vines - early	Olives	Citrus Spring application	Citrus Autumn application
D3	01/04-01/05	01/10-31/10	-	-	-	-
D4	06/04-06/05	01/10-31/10	-	-	-	-
D5	18/03-17/04	01/10-31/10	-	-	-	-
D6			01/03-31/03	01/10-31/10	01/03-31/03	01/10-31/10
R1	01/04-01/05	01/10-31/10	01/03-31/03	-	-	-
R2	01/03-31/03	01/10-31/10	01/03-31/03	-	-	-
R3	18/03-17/04	01/10-31/10	01/03-31/03	-	-	-
R4	01/03-31/03	01/03-31/10*	01/03-31/03	01/10-31/10	01/03-31/03	01/10-31/10

*This might be an error since all other scenarios were set to 01/10-31/10

Input parameters used for amitrole in FOCUS Step 1-4 are reported in the table below.

Table 8.6.2-4: Input parameters used for amitrole in Step 1-4

Parameter	Amitrole	Comment
Entry routes into surface water	Drainage Spray drift Runoff	Drainage Spray drift Runoff
Molecular weight [g mol ⁻¹]	84.08	Review Report (2000)
Water solubility [mg L ⁻¹]	264000	Review Report (2000)
Vapour pressure [Pa] at 20°C	3.3 x 10 ⁻⁵	Review Report (2000)
DEGRADATION IN SOIL		
DT ₅₀ (soil) [d]	23	Laboratory median value, as initially calculated by the applicant (see Table 8.1.2-5)
Temperature correction function Reference temperature [°C] MACRO: [K ⁻¹] PRZM: Q ₁₀ [-]	20 0.079 2.58	FOCUS recommendation
Moisture correction function Reference moisture [-] PRZM / MACRO: moisture exponent [-]	pF 2 0.7	FOCUS recommendation
SORPTION TO SOIL		
K _{loc} [L kg ⁻¹]	114	New data from Menerling, 2012
1/n [-]	0.808	New data from Menerling, 2012
DEGRADATION IN AQUATIC SYSTEMS		
DT ₅₀ water [d] (Step 2-3)	77	Recalculated DT50 according FOCUS kinetic guidance
DT ₅₀ sediment [d] (Step 2-3)	112	Recalculated DT50 according FOCUS kinetic guidance
DT ₅₀ whole system [d] (Step 1)	88	Recalculated DT50 according FOCUS kinetic guidance
DT ₅₀ crop [d] (Step 3)	10	FOCUS recommendation
Temperature correction function Reference temperature [°C] TOXSWA: activation energy [J mol ⁻¹]	20 65400	FOCUS recommendation
MANAGEMENT RELATED PARAMETERS		
Crop uptake factor [-]	0.5	FOCUS recommendation
Wash off coefficient [cm ⁻¹]	0.5	FOCUS recommendation

When necessary, mitigation measures were included in Step 4. They consisted on non treated buffer zone associated with vegetated filter strips.

Table 8.6.2-5: Used mitigation parameters for Step 4 calculations

Buffer Length	Mitigation Type	Spray drift mitigation	Run-off mitigation (fractional reduction)
5 m	Spraydrift & Runoff	5 m no spray buffer zone	0.5 for run-off and 0.5 for erosion
10 m	Spraydrift & Runoff	10 m no spray buffer zone	0.6 for run-off and 0.85 for erosion
15 m	Spraydrift & Runoff	15 m no spray buffer zone	0.8 for run-off and 0.95 for erosion
20 m	Spraydrift & Runoff	20 m no spray buffer zone	0.8 for run-off and 0.95 for erosion

□ Findings

Results in FOCUS Step 1-2 for vines are reported below (no PEC_{sw} with FOCUS Step 1-2 are reported for other crops in the reports).

Table 8.6.2-6: Maximum predicted concentrations of amitrole in surface water (PEC_{sw} actual and 21-day twa) and sediment (PEC_{sed} actual and 21-day twa) - Vine - FOCUS steps 1-2

FOCUS crop scenario	Step	Appl. rate [kg a.s./ha]	Region and season of appl.	Maximum PEC _{sw} actual [µg/L]	21-day twa PEC _{sw} [µg/L]	Maximum PEC _{sed} actual [µg/kg]	21-day twa PEC _{sed} [µg/kg]
Vine - early	1	0.992	n.r.	295.96	271.72	333.42	309.52
	2		N EU, Oct.-Feb	135.04	123.16	152.61	139.58
			S EU, Oct.-Feb	109.60	99.90	123.78	113.22
Vine - late	1	0.992	n.r.	313.58	285.88	350.72	325.18
	2		N EU, Oct.-Feb	150.49	136.68	169.35	154.89
			S EU, Oct.-Feb	125.04	113.42	140.51	128.52

n.r. not relevant

N EU northern Europe - S EU southern Europe

Results in FOCUS Step 3 are reported below.

Table 8.6.2-7: Maximum predicted concentrations of amitrole in surface water (PEC_{sw} actual and 21-day twa) and sediment (PEC_{sed} actual) – Pome fruits, early - FOCUS steps 3

Crop & FOCUS crop scenario	Step	Scenario	Water body	PEC _{sw} global max. actual concentration [µg/L]	PEC _{sw} 21-day twa concentration [µg/L]	PEC _{sed} global max. actual concentration [µg/kg]
Pome fruits Early	3	D3	Ditch	76.980	3.713	18.007
		D4	Pond	4.693	4.118	9.942
		D4	Stream	73.747	0.207	2.707
		D5	Pond	4.725	4.131	10.030
		D5	Stream	74.651	0.154	1.889
		R1	Pond	4.682	4.005	8.976
		R1	Stream	62.288	0.515	5.701
		R2	Stream	82.515	0.358	4.165
		R3	Stream	87.700	1.161	10.536
		R4	Stream	62.302	0.518	5.730

Table 8.6.2-8: Maximum predicted concentrations of amitrole in surface water (PEC_{sw} actual and 21-day twa) and sediment (PEC_{sed} actual) – Pome fruits, late - FOCUS steps 3

Crop & FOCUS crop scenario	Step	Scenario	Water body	PEC _{sw} global max. actual concentration [µg/L]	PEC _{sw} 21-day twa concentration [µg/L]	PEC _{sed} global max. actual concentration [µg/kg]
Pome fruits Late	3	D3	Ditch	36.445	3.148	12.048
		D4	Pond	5.919	5.713	17.474
		D4	Stream	36.499	3.602	6.993
		D5	Pond	2.513	2.329	7.053
		D5	Stream	39.492	0.984	6.479
		R1	Pond	1.632	1.399	3.884
		R1	Stream	28.001	0.287	3.119
		R2	Stream	37.164	0.485	2.641
		R3	Stream	39.467	1.213	6.083
		R4	Stream	27.792	0.231	2.663

Table 8.6.2-9: Maximum predicted concentrations of amitrole in surface water (PEC_{sw} actual and 21-day twa) and sediment (PEC_{sed} actual) – Citrus, spring application - FOCUS steps 3

Crop & FOCUS crop scenario	Step	Scenario	Water body	PEC _{sw} global max. actual concentration [µg/L]	PEC _{sw} 21-day twa concentration [µg/L]	PEC _{sed} global max. actual concentration [µg/kg]
Citrus Spring	3	D6	Ditch	36.447	2.167	9.845
		R4	Ditch	27.717	0.216	2.513

Table 8.6.2-10: Maximum predicted concentrations of amitrole in surface water (PEC_{sw} actual and 21-day twa) and sediment (PEC_{sed} actual) – Citrus, autumn application - FOCUS steps 3

Crop & FOCUS crop scenario	Step	Scenario	Water body	PEC _{sw} global max. actual concentration [µg/L]	PEC _{sw} 21-day twa concentration [µg/L]	PEC _{sed} global max. actual concentration [µg/kg]
Citrus Autumn	3	D6	Ditch	36.627	13.144	25.304
		R4	Ditch	25.271	0.121	0.765

Table 8.6.2-11: Maximum predicted concentrations of amitrole in surface water (PEC_{sw} actual and 21-day twa) and sediment (PEC_{sed} actual) – Olives - FOCUS steps 3

Crop & FOCUS crop scenario	Step	Scenario	Water body	PEC _{sw} global max. actual concentration [µg/L]	PEC _{sw} 21-day twa concentration [µg/L]	PEC _{sed} global max. actual concentration [µg/kg]
Olives	3	D6	Ditch	16.916	6.053	12.480
		R4	Ditch	11.690	0.0663	0.387

Table 8.6.2-12: Maximum predicted concentrations of amitrole in surface water (PEC_{sw} actual and 21-day twa) and sediment (PEC_{sed} actual) – Vines, early - FOCUS steps 3

Crop & FOCUS crop scenario	Step	Scenario	Water body	PEC _{sw} global max. actual concentration [µg/L]	PEC _{sw} 21-day twa concentration [µg/L]	PEC _{sed} global max. actual concentration [µg/kg]
Vine Early	3	D6	Ditch	5.902	0.579	2.486
		R1	Pond	0.191	0.164	0.523
		R1	Stream	4.123	0.0411	0.493
		R2	Stream	5.419	0.103	0.904
		R3	Stream	5.757	0.0726	0.785
		R4	Stream	4.086	0.0321	0.405

Step 4 calculations were performed for Citrus and Pome fruits only. Results are presented below.

Table 8.6.2-13: Maximum predicted concentrations of amitrole in surface water (PEC_{sw} actual and 21-day twa) and sediment (PEC_{sed} actual) – Pome fruits -early - FOCUS steps 4

Crop & FOCUS crop scenario	Step	Scenario	Water body	PEC _{sw} global max. actual concentration [µg/L]		
				5 m no spray buffer zone +	10 m buffer zone	15 m buffer zone
Pome fruits Early	4	D3	Ditch	60.489	37.144	16.711
		D4	Pond	5.282	2.901	1.536
		D4	Stream	63.364	38.913	17.508
		D5	Pond	5.314	2.933	1.568
		D5	Stream	64.143	39.397	17.734
		R1	Pond	5.271	2.890	1.526
		R1	Stream	53.518	32.865	14.785
		R2	Stream	70.897	43.537	19.587
		R3	Stream	75.352	46.273	20.817
		R4	Stream	53.530	32.872	14.798

Table 8.6.2-14: Maximum predicted concentrations of amitrole in surface water (PEC_{sw} actual and 21-day twa) and sediment (PEC_{sed} actual) – Pome fruits -late - FOCUS steps 4

Crop & FOCUS crop scenario	Step	Scenario	Water body	PEC _{sw} global max. actual concentration [µg/L]			
				5 m buffer zone	10 m buffer zone	15 m buffer zone	20 m buffer zone
Pome fruits Late	4	D3	Ditch	24.601	10.993	5.550	3.292
		D4	Pond	6.017	5.673	5.519	5.441
		D4	Stream	28.482	12.727	8.159	8.159
		D5	Pond	2.513	2.513	2.513	2.513
		D5	Stream	30.817	13.770	6.953	4.786
		R1	Pond	1.867	1.035	0.661	0.471
		R1	Stream	21.850	9.763	4.930	3.013
		R2	Stream	29.000	12.958	6.543	3.999
		R3	Stream	30.798	13.761	6.948	4.246
		R4	Stream	21.687	9.690	4.893	2.990

Table 8.6.2-15: Maximum predicted concentrations of amitrole in surface water (PEC_{sw} actual and 21-day twa) and sediment (PEC_{sed} actual) – Citrus, spring application- FOCUS steps 4

Crop & FOCUS crop scenario	Step	Scenario	Water body	PEC _{sw} global max. actual concentration [µg/L]		
				5 m buffer zone	10 m buffer zone	15 m buffer zone
Citrus Spring	4	D6	Ditch	24.652	11.101	5.681
		R4	Ditch	21.628	9.664	4.880

Table 8.6.2-16: Maximum predicted concentrations of amitrole in surface water (PEC_{sw} actual and 21-day twa) and sediment (PEC_{sed} actual) – Citrus, autumn application- FOCUS steps 4

Crop & FOCUS crop scenario	Step	Scenario	Water body	PEC _{sw} global max. actual concentration [µg/L]		
				5 m buffer zone	10 m buffer zone	15 m buffer zone
Citrus Autumn	4	D6	Ditch	24.724	11.047	5.578
		R4	Ditch	19.720	8.811	4.449

□ RMS comments

Note: there are some inconsistencies between what is reported in the study report and the input/output files. When needed, RMS corrected the summary with data found in the input/output files.

The main deviations of the study are reported below.

The study was not conducted as requested by RMS: the dose was divided by 3 for the entries by drift, drainage and run-off, whereas it should have been done for drainage and run-off only. Therefore, entries by drift may be underestimated. On the other hand, the applicant used the default drift entries for pome/stone fruits, vines, citrus and olives, which are conservative with regards to the use of amitrole which is applied on the ground.

For R scenarios, the application method CAM 1 (application soil linear) was selected, and so it is expected that no interception is taken into account. However, for D scenarios, interception is calculated by the model and depending on the crops, it can reach 80%. This is not considered acceptable.

Based on the above points, it is difficult to determine whether the calculations proposed by the applicant are conservative or not. **Therefore, values cannot be validated.** The study is not acceptable.

In addition, the following deviations were observed in the input parameters:

- The soil DT50 was set to 23 days. This is a conservative value compared to the geometric mean of 7.4 days that would have been used by RMS.
- The Koc was set to 114 mL/g (value from Menerling, 2012), whereas a median value of 111 mL/g would have been used by RMS. This will have no significant impact on the PEC_{sw} values.
- The DT50 value used for water and sediment represents dissipation and not degradation and so cannot be accepted. In addition, the origin of the DT50 used for total system and sediment is not clear (although it is not far from the geometric mean, it does not correspond to geometric mean nor to a specific value from one of the system). For Step 3, it would have been more appropriate to use the geometric mean from total system (86.2 days) for the water compartment, and a conservative value of 1000 days for the sediment compartment.

It is noted that the FOCUS Landscape and Mitigation proposes values of fractional reduction for vegetated filter strip of 10-12 m (0.6 and 0.85 for run-off and erosion, respectively) and 18-20 m (0.8 and 0.95 for run-off and erosion, respectively). Therefore, the buffer zone defined as “15 m” by the applicant corresponds to 15 m no spray buffer zone and 18-20 m vegetated filter strip.

Since the studies provided do not answer to the RMS request's, the applicant is asked to provide new PEC_{sw} calculations. In absence of validated PEC_{sw}, the exposure to surface water cannot be finalised.

It is highlighted that an additional study on PEC_{sw} calculations (Kind, 2012 – Report Number 12036-NUF) was finally provided by the applicant at the end of December 2012. However, since it was too late in the process and the DAR had already been sent for comments to co-RMS, the study was not summarized nor assessed by RMS.

B.8.6.2.1.2. PEC_{sw} for non crop uses

Two situations have to be considered for non crop uses:

- The application is done on permeable surfaces: although requested by RMS, no specific assessment was proposed by the applicant. In addition, no PEC_{sw} is acceptable for agricultural uses, and therefore it cannot be argued that the calculations performed for agricultural uses cover permeable surfaces. **The applicant must provide PEC_{sw}.**
- The application is done on impermeable surfaces. The standard calculations with the FOCUS tools are not appropriate. As far as we know, there is no EU agreed tool for these uses. It is proposed to use the model HardSPEC, used by CRD. The latest version of the model (v. 1.4.2) was used.

Calculations for impermeable surfaces are presented below.

Bertrand, M., 2011c – Predicted environmental concentrations of Amitrole and 1,2,4-triazole in groundwater (PEC_{gw}), surface water (PEC_{sw}) and sediment (PEC_{sed}) following applications on non crops using HardSPEC 1.2. Document n° NUFGW03112011.

Since calculations were performed with “old” endpoints and with an old version of HardSPEC, the applicant was asked to provide new simulations. The study is therefore superseded and not summarised.

The following additional study was provided by the applicant and is summarised below.

Comoretto, L., 2012e – Predicted environmental concentrations of Amitrole in groundwater (PEC_{gw}), surface water (PEC_{sw}) and sediment (PEC_{sed}) following application on non crop using HardSPEC 1.4.2. Document n° NUFHS22072012A.

- ☐ **Guidelines:** not reported
- ☐ **GLP:** Not relevant
- ☒ **Deviations:** Yes, see comments

❑ **Acceptability:** No

❑ **Method**

PEC_{sw} and PEC_{sed} for Amitrole following applications on non crop uses were calculated using the model HardSPEC 1.4.2. The maximum application rate of Amitrole (2977 g/ha) was used for PEC_{sw} calculation. For PEC_{sed} calculation, the application rate was corrected by the maximum occurrence observed in sediment during the water/sediment studies (14.4%). Therefore, an application rate of 429 g/ha was used.

The following input parameters were used in the calculations.

Table 8.6.2-17: Input parameters used for amitrole in HardSPEC

Herbicide properties	Value	Comment
Herbicide name	amitrole	
% of applied amount impacting as spray drift. Urban & Major road	2.8	Default value
% of domestic scenario areas treated	10	Default value
Measured K _p asphalt (mg m ⁻²)	not known	-
Measured K _p concrete (mg m ⁻²)	not known	-
soil k _{oc} (mL g ⁻¹)	114	Value from Menerling, 2012
solubility (mg L ⁻¹)	264000	Review Report (2000)
Specific Gravity	1.138	Review Report (2000)
DT50 in soil (days)	23	Laboratory median value as initially calculated by the applicant (see Table 8.1.2-5)
DT50 on hard surfaces (days)	not known	
DT50 in sediment (days)	118*	-
DT50 in water (days)	67*	-
Application amount (g/ha)		
Urban	2977 / 429	For PEC _{sw} / For PEC _{sed}
Sub-urban (domestic use)	2977 / 429	For PEC _{sw} / For PEC _{sed}
Road	2977 / 429	For PEC _{sw} / For PEC _{sed}
Railway	2977 / 429	For PEC _{sw} / For PEC _{sed}
Uncertainty factors		
Fraction of 774.7 m ² railway track target area actually sprayed	1	Default value
Run-off attenuation factor applied to leached load from ballast	1	Default value

* Values of 112 and 77 for water and sediment respectively are mentioned in the report for PEC_{sw} calculations; values of 118 and 77 days for water and sediment respectively are mentioned in the report for PEC_{sed} calculations. However it was checked in the excel spreadsheets that the values used were 118 and 67 respectively.

❑ **Findings**

Results are reported in the following table.

Table 8.6.2-18: PEC_{sw} and PEC_{sed} calculated for amitrole using HardSPEC

	Acute (24 hrs) concentration		Application day PEC _{sw} from spray drift (mg l ⁻¹)
	Water phase (µg / L)	Sediment phase (µg / kg)	
Urban stream	452.627	74.304	27.309
Urban pond	42.610	7.022	0.172
Major road stream	232.237	38.152	19.399
Domestic stream	98.716	16.217	0.000
Railway ditch leaching	7.821	0.195	7.821
Railway ditch runoff	7.821	0.725	7.821

□ RMS comments

The following deviations were identified:

- The soil DT50 was set to 23 days. This is a conservative value compared to the geometric mean of 7.4 days that would have been used by RMS.
- The Koc was set to 114 mL/g (value from Menerling, 2012), whereas a median value of 111 mL/g would have been used by RMS. This will have no impact on the PEC_{sw} values.
- The origin of the DT50 used for water and sediment is not clear (it does not correspond to the geometric mean nor to a specific value from one of the system). In addition, DT50 represent dissipation and not degradation. Using the same procedure as for FOCUS Step 2, RMS would have used the geometric mean from the total system (86.2 days) for each compartment.
- PEC_{sed} calculations cannot be accepted. Indeed, the model HardSPEC directly calculates the proportion of active substance which reaches the sediment based on Koc value. Therefore, the application rate should not be corrected by the maximum occurrence in sediment.

Consequently, PEC_{sw} and PEC_{sed} were recalculated by RMS. The model HardSPEC v.1.4.2 was used, with the following input parameters.

Table 8.6.2-19: Input parameters used for amitrole in HardSPEC (RMS)

Herbicide properties	Value	Comment
Herbicide name	amitrole	
% of applied amount impacting as spray drift. Urban & Major road	2.8	Default value
% of domestic scenario areas treated	10	Default value
Measured Kp asphalt (mg m^{-2})	not known	
Measured Kp concrete (mg m^{-2})	not known	
soil koc (mL g^{-1})	111	Median
solubility (mg L^{-1})	264000	Review Report (2000)
Specific Gravity	1.138	Review Report (2000)
DT50 in soil (days)	7.4	Geometric mean
DT50 on hard surfaces (days)	not known	
DT50 in sediment (days)	86.2	Geometric mean from total system
DT50 in water (days)	86.2	Geometric mean from total system
Application amount (g/ha)		
Urban	2977	-
Sub-urban (domestic use)	2977	-
Road	2977	-
Railway	2977	-
Uncertainty factors		
Fraction of 774.7 m^2 railway track target area actually sprayed	1	Default value
Run-off attenuation factor applied to leached load from ballast	1	Default value

Results are reported in the following table.

Table 8.6.2-20: PEC_{sw} and PEC_{sed} calculated for amitrole using HardSPEC (RMS)

	Acute (24 hrs) concentration		Application day PEC _{sw} from spray drift (mg l^{-1})
	Water phase ($\mu\text{g L}^{-1}$)	Sediment phase ($\mu\text{g / kg}$)	
Urban stream	453.782	503.335	27.309
Urban pond	42.733	47.350	0.172
Major road stream	233.210	258.863	19.399
Domestic stream	76.356	84.755	0.000
Railway ditch leaching	7.821	0.877	7.821
Railway ditch runoff	7.821	3.616	7.821

B.8.6.2.2. Predicted environmental concentrations of Amitrole metabolites in surface water

Calculations are presented by the applicant for 1,24,-triazole. It is reminded that RMS considers that this metabolite will not be formed in significant amounts for the sustained uses, and therefore do not need to be included in the risk assessment. However, calculations are presented for information.

B.8.6.2.2.1 PEC_{sw} for agricultural uses

The following studies were provided by the applicant.

Comoretto, L., 2012k – Predicted environmental concentrations (PEC) of the metabolite 1,2,4-triazole in surface water and sediment (PEC_{sw} and PEC_{sed}) according to FOCUS surface water scenarios after applications on citrus. Document n° NUFWS19072012A.

Comoretto, L., 2012l – Predicted environmental concentrations (PEC) of the metabolite 1,2,4-triazole in surface water and sediment (PEC_{sw} and PEC_{sed}) according to FOCUS surface water scenarios after applications on olives trees. Document n° NUFWSW19072012B.

Comoretto, L., 2012m – Predicted environmental concentrations (PEC) of the metabolite 1,2,4-triazole in surface water and sediment (PEC_{sw} and PEC_{sed}) according to FOCUS surface water scenarios after applications on vines. Document n° NUFWSW19072012C.

Comoretto, L., 2012n – Predicted environmental concentrations (PEC) of the metabolite 1,2,4-triazole in surface water and sediment (PEC_{sw} and PEC_{sed}) according to FOCUS surface water scenarios after applications on orchards. Document n° NUFWSW19072012D.

- ❑ **Guidelines:** FOCUS SW (2001)
- ❑ **GLP:** Not relevant
- ❑ **Deviations:** some deviations identified but results are conservative (see comments)
- ❑ **Acceptability:** Yes
- ❑ **Method**

PEC_{sw} and PEC_{sed} for 1,2,4-triazole were calculated using FOCUS Step 1-2 version 1.1. Since 1,2,4-triazole is a soil photodegradation product, it is formed only in the upper soil layer. Therefore, for PEC_{sw} calculations, it was considered as an active ingredient directly added on soil surface.

The maximum application rate of Amitrole (2977 g/ha) was corrected for the soil maximum occurrence of 1,2,4-triazole (9.9%) and molecular ratio (69.1/84.08). In addition, since amitrole is applied by under the rows only, the application rate was factored by 1/3 for band applications.

The following application scheme was used for Step 1. Step 2 was not performed.

Table 8.6.2-21: Application scheme used for 1,2,4-triazole in FOCUS Step 1

Crop	Pome/stone fruits (early & late) – Citrus – Vines, early – Olives
Application rate (g/ha)	815 (2977 x 1/3 x 0.099 x 69.1/84.08)
Number of applications	1

The following input parameters were used for 1,2,4-triazole in Step 1.

Table 8.6.2-22: Input parameters used for 1,2,4-triazole in FOCUS Step 1

Parameter	Value
Water solubility (mg/L)	730000
K _{oc} (mL/g)	89
DT50 in water/sediment system (days)	1000

❑ Findings

Main results are summarised in the following table.

Table 8.6.2-23: Maximum predicted concentrations of 1,2,4-triazole in surface water (PEC_{sw} actual and 21-day twa) and sediment (PEC_{sed} actual and 21-day twa) - FOCUS Step 1

FOCUS crop scenario	Step	Maximum PEC _{sw} actual [µg/L]	21-day twa PEC _{sw} [µg/L]	Maximum PEC _{sed} actual [µg/kg]	21-day twa PEC _{sed} [µg/kg]
Pome fruits early	1	32.22	31.17	21.61	27.57
Pome fruits late, citrus and olives	1	28.56	27.91	21.61	24.75
Vineyards	1	25.02	24.76	21.61	22.02

❑ RMS comments

RMS agrees that the applied dose can be corrected by a factor of 1/3 for drainage and run-off entries to take into account the banded application. However, the whole dose should be used for drift entries. Nevertheless, metabolite 1,2,4-triazole is only formed in soil but not in water/sediment systems. As a consequence, the only relevant entries of 1,2,4-triazole into surface water are drainage and run-off. The PEC_{sw} proposed by the applicant are overestimated since they also take into account entries by drift. The approach proposed by the applicant is considered conservative in this case. Since the risk assessment for aquatic organisms is acceptable with these conservative PEC_{sw}, no refinement is proposed.

It is also noted that calculations were not performed for the crop vines, late. Since the only change between vines early and late concerns drift, and as explained above drift is not relevant for 1,2,4-triazole, there is no need to perform new calculations.

B.8.6.2.2.2. PEC_{sw} for non crop uses

Two situations have to be considered for non crop uses:

- The application is done on permeable surfaces: A study originally provided for agricultural uses with FOCUS Step 1 but performed on the scenario grass is available. It is considered that it can be used for non crop uses.
- The application is done on impermeable surfaces. The standard calculations with the FOCUS tools are not appropriate. As far as we know, there is no EU agreed tool for these uses. It is proposed to use the model HardSPEC, used by CRD. The latest version of the model (v. 1.4.2) was used.

➤ Permeable surfaces

Bertrand, M., 2011f – Predicted environmental concentrations (PEC) of the metabolite 1,2,4-triazole in surface water and sediment (PEC_{sw} and PEC_{sed}) according to FOCUS surface water scenarios after applications on olive, trees, pome and stone fruits and vines. Document n° NUFWS071111.

❑ **Guidelines:** FOCUS SW (2001)

❑ **GLP:** Not relevant

❑ **Deviations:** some deviations identified but results are conservative (see comments)

❑ **Acceptability:** Yes

❑ Method

PEC_{sw} and PEC_{sed} for 1,2,4-triazole were calculated using FOCUS Step 1-2 version 1.1. Since 1,2,4-triazole is a soil photodegradation product, it is formed only in the upper soil layer. Therefore, for PEC_{sw} calculations, it was considered as an active ingredient directly added on soil surface.

The maximum application rate of Amitrole (2977 g/ha) was corrected for the soil maximum occurrence of 1,2,4-triazole (9.9%). In addition, since amitrole is applied by under the rows only, the application rate was multiplied by 0.3 for band applications (30%).

The following application scheme was used for Step 1. Step 2 was not performed.

Table 8.6.2-24: Application scheme used for 1,2,4-triazole in FOCUS Step 1

Crop	Grass and alfalfa
Application rate (g/ha)	88.5 (2977 x 0.3 x 0.099)
Number of applications	1

The following input parameters were used for 1,2,4-triazole in Step 1.

Table 8.6.2-25: Input parameters used for 1,2,4-triazole in FOCUS Step 1

Parameter	Value
Water solubility (mg/L)	730000
Koc (mL/g)	89
DT50 in water/sediment system (days)	1000

□ Findings

Main results are summarised in the following table.

Table 8.6.2-26: Maximum predicted concentrations of 1,2,4-triazole in surface water (PEC_{sw} actual and 21-day twa) and sediment (PEC_{sed} actual and 21-day twa) - FOCUS Step 1

FOCUS crop scenario	Step	Maximum PEC _{sw} actual [µg/L]	21-day twa PEC _{sw} [µg/L]	Maximum PEC _{sed} actual [µg/kg]	21-day twa PEC _{sed} [µg/kg]
Grass and alfalfa	1	27.18	26.90	23.47	23.93

□ RMS comments

As for agricultural uses, it is considered that only 30% of the surface is treated and therefore the applied dose can be corrected by 0.3 for drainage and run-off entries to take into account the banded application (zRMS notes that a factor of 1/3 was used for agricultural uses, which is slightly different from 30%). However, the whole dose should be used for drift entries. Nevertheless, metabolite 1,2,4-triazole is only formed in soil but not in water/sediment systems. As a consequence, the only relevant entries of 1,2,4-triazole into surface water are drainage and run-off. The PEC_{sw} proposed by the applicant are overestimated since they also take into account entries by drift. The approach proposed by the applicant is considered conservative in this case. Since the risk assessment for aquatic organisms is acceptable with these conservative PEC_{sw}, no refinement is proposed.

Note: Results from Step 2 calculations are reported in the study summary, however the input/output files were not provided and so could not be checked by RMS. Therefore, they are not reported here.

➤ Impermeable surfaces

Bertrand, M., 2011c – Predicted environmental concentrations of Amitrole and 1,2,4-triazole in groundwater (PEC_{gw}), surface water (PEC_{sw}) and sediment (PEC_{sed}) following applications on non crops using HardSPEC 1.2. Document n° NUFGW03112011.

Since calculations were performed with “old” endpoints and with an old version of HardSPEC, the applicant was asked to provide new simulations. The study is therefore superseded and not summarised.

The following additional study was provided by the applicant and is summarised below.

Comoretto, L., 2012f – Predicted environmental concentrations (PEC) of 1,2,4-triazole in groundwater (PEC_{gw}), surface water (PEC_{sw}) and sediment (PEC_{sed}) following application on non crop using HardSPEC 1.4.2. Document n° NUFHS22072012B.

□ **Guidelines:** not reported

□ **GLP:** Not relevant

❑ **Deviations:** none identified

❑ **Acceptability:** Yes

❑ **Method**

PEC_{sw} and PEC_{sed} for 1,2,4-triazole following applications on non crop uses were calculated using the model HardSPEC 1.4.2. The maximum application rate of Amitrole (2977 g/ha) was corrected for the soil maximum occurrence of 1,2,4-triazole (9.9%) and molecular ratio (69.1/84.08), giving an application rate of 242 g/ha of 1,2,4-triazole.

The following input parameters were used in the calculations.

Table 8.6.2-27: Input parameters used for 1,2,4-triazole in HardSPEC

Herbicide properties	Value	Comment
Herbicide name	1,2,4-triazole	
% of applied amount impacting as spray drift. Urban & Major road	2.8	Default value
% of domestic scenario areas treated	10	Default value
Measured K _p asphalt (mg m ⁻²)	not known	-
Measured K _p concrete (mg m ⁻²)	not known	-
soil k _{oc} (mL g ⁻¹)	89	Mean K _{foc} (EU agreed endpoints)
solubility (mg L ⁻¹)	730000	Agreed EU endpoint
Specific Gravity	1.138	The same value as for amitrole was used
DT50 in soil (days)	60.5	Mean value from the slow phases of DFOP, field normalised DT50
DT50 on hard surfaces (days)	not known	
DT50 in sediment (days)	1000	Conservative value
DT50 in water (days)	1000	Conservative value
Application amount (g/ha)		
Urban	242	-
Sub-urban (domestic use)	242	-
Road	242	-
Railway	242	-
Uncertainty factors		
Fraction of 774.7 m ² railway track target area actually sprayed	1	Default value
Run-off attenuation factor applied to leached load from ballast	1	Default value

❑ **Findings**

Results are reported in the following table.

Table 8.6.2-28: PEC_{sw} and PEC_{sed} calculated for 1,2,4-triazole using HardSPEC

	Acute (24 hrs) concentration		Application day PEC _{sw} from spray drift (mg l ⁻¹)
	Water phase (µg / L)	Sediment phase (µg / kg)	
Urban stream	37.615	33.454	2.220
Urban pond	3.589	3.202	0.014
Major road stream	19.570	17.417	1.577
Domestic stream	8.922	7.940	0.000
Railway ditch leaching	0.636	0.128	0.636
Railway ditch runoff	0.636	0.454	0.636

□ RMS comments

The proposed calculations are acceptable. It is noted that they are conservative for 1,2,4-triazole since the entries by drift are taken into account, whereas they should not (see comments at the end of B.8.6.2.2.1).

B.8.6.2.1. Summary of PEC_{sw} for Amitrole and its metabolites

For agricultural uses, the calculations initially provided by the applicant for PEC_{sw} for Amitrole were not considered acceptable. The applicant was asked to provide new PEC_{sw} calculations, taking into account the specificities of the sustained uses (crop interception of 0%, considering the full dose for the drift entries and a lower dose (1/3) for the drainage and run-off entries, correcting the drift entries to take into account that amitrole is applied on the ground and not on foliage, as recommended by FOCUS SW guidance document).

The additional calculations provided by the applicant do not answer to the RMS' request and cannot be validated by RMS. Therefore, **the applicant is asked to provide new PEC_{sw} calculations. In absence of validated PEC_{sw}, the exposure to surface water cannot be finalized.**

For 1,2,4-triazole, PEC_{sw} were calculated using FOCUS Step 1. PEC_{sw} ranged between 25.02 to 32.22 µg/L.

For non agricultural uses on permeable surfaces, no specific calculations were provided by the applicant for amitrole, although requested by RMS. Therefore, **the applicant is asked to provide PEC_{sw} calculations.** For 1,2,4-triazole, PEC_{sw} were calculated using FOCUS Step 1 and are estimated to 27.18 µg/L.

For non agricultural uses on impermeable surfaces, PEC_{sw} were calculated using HardSPEC. Depending on the scenarios considered, PEC_{sw} ranged between 7.821 and 453.782 µg/L for Amitrole, and between 0.636 and 37.615 µg/L for 1,2,4-triazole.

B.8.7. FATE AND BEHAVIOUR IN AIR (ANNEX IIA 7.2.2, ANNEX IIIA 9.3)

B.8.7.1. Vapour pressure

No additional study was submitted, please refer to the DAR for details. A summary of fate and behaviour in air is provided in B.8.7.4.

B.8.7.2. Photolysis in air

No additional study was submitted, please refer to the DAR for details. A summary of fate and behaviour in air is provided in B.8.7.4.

B.8.7.3. Volatilisation from soil surface or plants

No additional study was submitted, please refer to the DAR for details. A summary of fate and behaviour in air is provided in B.8.7.4.

B.8.7.4. Summary of fate and behaviour in air

No new study on the fate and behavior of Amitrole in air was provided. Based on the vapour pressure of Amitrole of 3.3×10^{-5} Pa at 20°C, it can be concluded that significant volatilisation from soil is not to be expected. However, volatilization from plant surfaces may occur, according to the FOCUS Air criteria. This is confirmed by laboratory experiments, in which volatilization from soil was negligible after 24 hours and volatilization from plant surface was estimated to 11% AR after 24 hours.

The chemical lifetime of Amitrole in the troposphere was calculated to be 4.8 hours, assuming an OH concentration of 5.10^5 /cm³ over 24 hours. Therefore, an accumulation of Amitrole in the air is not to be expected.

B.8.8. PREDICTED ENVIRONMENTAL CONCENTRATIONS IN AIR (PEC_A) (ANNEX IIA 9.3)

Based on vapour pressure (3.3×10^{-5} Pa at 20°C), Henry's Law Constant (1.76×10^{-8} Pa.m³.mol⁻¹) and information on volatilisation from plants and soil, PEC in air are expected to be negligible.

B.8.9. DEFINITION OF THE RESIDUE (ANNEX IIA 7.3)

The following residue definition is proposed:

Soil: Amitrole, 1,2,4-triazole
 Surface Water: Amitrole, 1,2,4-triazole
 Sediment: Amitrole
 Ground water: Amitrole, 1,2,4-triazole
 Air: Amitrole

B.8.10. MONITORING DATA (ANNEX IIA 7.4)

Several monitoring studies were performed:

- o 1996-1997 (KIIA 7.12/01, Quérou R., Touratier C. and Ambrosi D., 1998) (already summarised in the addendum to the DAR)
- o 1998 (KIIA 7.12/02, Touratier C., 1999) (already summarised in the addendum to the DAR)
- o 1999 (KIIA 7.12/03, Dano A.-S. and Touratier C., 2000).

The results of those studies were compiled by A.-S. Dano in 2004.

A summary of these reports is given below.

Querou, C., Touratier, C., Ambrosi, D., 1998 – Amitrole: groundwater survey 1996-1997. Nufarm (formerly CFPI) dossier reference 145.

Touratier, C., 1999 – Amitrole: groundwater survey 1998. Nufarm (formerly CFPI) dossier reference 169.

Dano, A.S., Touratier, C., 2000 – Amitrole: Water monitoring 1999 groundwater and treated surface water. CPFI Agro report n°CT/ASD00318.

Dano, A.S., 2004 – Amitrole: groundwater survey 1996-2001. Nufarm report n°ASD/04-094.

□ Method

The reports of the ECCO-meeting groups concluded that, because of its physico-chemical properties and despite its rapid degradation in soils, amitrole has a potential for leaching into ground water. Therefore monitoring data had to be generated.

CFPI AGRO decided to conduct a water survey of ground water in France for 4 years, and started in 1996. This monitoring has been pursued by CFPI Nufarm and Nufarm S.A. until 2001.

The sites of sampling were selected according to the significant quantity of amitrole used in various parts of France and when it was known that some other pesticides had been already detected. Ground water sites selected can be considered as vulnerable sites for different reasons : sandy soils, soils with low organic matter, areas

prone to excessive preferential flow, shallow depth to ground water, and were chosen in order to assess possible contamination of water by amitrole under worst-case conditions.

A total of 14 different sites have been chosen during the monitoring from 1996 to 2001. Some of them were used by water companies for supplying drinking water. Figure 8.7.4-1 shows the geographical location of the selected sampling sites.

The survey had been initially planned for 4 years and was stopped for all sites at the end of 1999, except for Vosne-Romanée, the only site where residues of amitrole were ever detected, where the survey had been prolonged for 2 years. In 2000, a site was added near Panjas, considered as a worst-case by its geographical, hydrogeological and pedological characteristics.

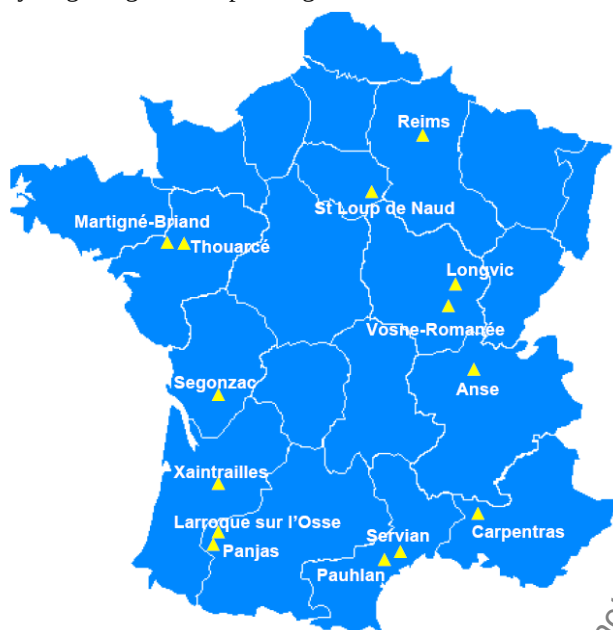


Figure 8.7.4-1: Geographical location of the groundwater sampling sites

Table 8.7.4-1 gives a summary of sampling for all sites during the survey from 1996 to 2001.

Table 8.7.4-1: Sampling summary

Sampling site		Number of samples					
		1996	1997	1998	1999	2000	2001
1	Longvic ¹	6	9				
2	Servian ¹	5	9				
3	Martigné-Briand		8	5	10		
4	Saint Loup de Naud		9	5	9		
5	Carpentras			5	7		
6	Thouarcé ²			5	-		
7	Anse			5	10		
8	Reims ³			5	10		
9	Vosne-Romanée			5	9*	10	12
10	Segonzac				10		
11	Xaintraillies				8		
12	Larroque sur l'Osse				8		
13	Pauhlan				9		
14	Panjas					10	

¹ Abandoned after 1997 because the LOQ of the method was 0.15 µg/L.

² Well closed in 1999.

³ Treated groundwater.

In 1996 samples were taken twice per month from mid-May to mid-August and in 1997 twice per month from mid-March to mid-August. From 1998 to 2000, ground water samples were taken in all locations once every

month from March to August. In 2000, samples were taken once every month from February until November and in 2001 once every month.

At each sampling date, the same procedure was followed. Sampling equipment was rinsed before each sampling. All precautions were taken to avoid any contamination. For each site, duplicate samples were taken in plastic bottles (0.5 L) equipped with an tamper-proof cap (results showed that there were no differences between plastic and glass flasks). Samples were kept refrigerated before analysis for a period of a few days to a maximum of 15 days. The duplicate of a set of two samples was used for confirmatory analysis only in case of positive result.

A short description of each site is given below, based on the available data.

Site 1 : Longvic (North-East, department : Cote d'Or). This site is a well located near the vineyard of 'Côte de nuits'. In 1997, a total amount of 86 tons of amitrole was applied in the department for the treatment of vineyards (area approximately of 14 000 ha) plus 105 kg 10 km around the sampling site for the treatment of non-cultivated areas and railways.

Site 2 : Servian (South, department : Hérault). This site is located in the vineyard of 'Côteaux du Languedoc'. In 1997, for the treatment of vineyards, a total amount of 85 tons of amitrole was applied in the department (total area : 103 600 ha), and 28 kg of amitrole 10 km around the sampling site for the treatment of railways.

Both sites are used by water companies for supplying drinking water. Sampling and analysis were done by CIRSEE and sites were abandoned after the first year because of the method of analysis.

Site 3 : Martigné-Briand (North-West, department : Maine et Loire) and **Site 6 : Thouarcé** (North-West, department : Maine et Loire). These two sites, distant from 5 kms, are located in the vineyards of 'Pays de Loire'. The ground water is an alluvial ground water, partly supplied by the river Loire. Wells are located at a depth of 12 and 24 meters (Martigné-Briand) and 6 and 13 meters (Thouarcé) in Cenomanien sands.

Both sites were chosen due to the use of amitrole in the department. In 1998, for the treatment of vineyards, a total amount of 34 tons of amitrole was applied in the department of Maine et Loire (on an area of approximately 18 000 ha). Additionally, an amount of 37.5 kg amitrole was applied 10 km around the sampling site, for treatment of non-cultivated areas. In 1999, a total of 10.5 metric tons of amitrole was applied in the department on an area of approximately 6 400 ha (vineyards and orchards).

Thouarcé sampling site has been abandoned in 1999, after the closure of the well.

Site 4 : St Loup de Naud (Source 'Glatigny' East of Paris , department : Seine-et-Marne). This site corresponds to a re-emergence of ground water located in limestone called 'calcaire de Champigny'.

This site is located in an area where amitrole is used only in non-cultivated areas. In 1998, a total amount of 18 kg amitrole was applied 10 km around from the sampling site.

Site 5 : Carpentras (South, department : Vaucluse). This site is located in the Southern vineyards of 'Côtes du Rhône'. The well is located in a market gardening area in the suburb of Carpentras. Not far from the Eastern border of the sampling site start the vineyards of 'Côtes du Ventoux'. The caught ground water is the alluvial ground water of Carpentras basin, mainly supplied by rainfall and irrigation and also by ground water coming down the Mount Ventoux. Its depth in this area is about 2 meters. This site is known to be contaminated by nitrates and herbicides.

In 1998, for the treatment of vineyards of 'Côtes du Rhône', a total amount of 36 tons of amitrole was applied. Additionally, as far as known, no amitrole was used for treatment of non-cultivated areas 10 km around the sampling site. In 1999, approximately 10 metric tons of amitrole were applied in the department on 3 800 ha.

Site 7 : Anse (South-East, department : Rhône). This site is located in the Southern vineyards of 'Beaujolais'. Soils of this area consist of alluvial deposits from the river Saône laying on clayey and calcareous mesozoic sediments.

In 1998, for the treatment of vineyards, a total amount of 38 tons of amitrole was applied in the Beaujolais vineyards. Additionally, an amount of 100 kg amitrole was applied 10 km around the sampling site for treatment of non-cultivated areas. In 1999, 27.2 metric tons of amitrole were applied in the department on 13 200 ha of vineyards.

Site 8 : Reims (North-East, department : Marne). This site is located North-East in the vineyards of Champagne. The ground water is a semi-confined body located in a layer of altered chalk situated itself under alluvial

deposits of clay and peat. The eight drillings supplying the plant go down to 30 meters into this chalk layer. The ground water is partly supplied by the river Vesle and a canal (Canal de l'Aisne à la Marne) which may be the origin of some pollution, and has thus to be considered as vulnerable to pollution. This ground water is the only one in our survey sampled after drinkability process (active carbon).

In 1998, for the treatment of vineyards, a total amount of 55 tons of amitrole was applied in the Champagne vineyards. Additionally, an amount of 133 kg amitrole was applied 10 km around the sampling site for treatment of non-cultivated areas. In 1999, 16 metric tons of amitrole were applied in the Champagne vineyards on approximately 6 200 ha. Additionally, an amount of 240 kg of amitrole was applied around the sampling site for treatment of non-cultivated areas.

Site 9 : Vosne-Romanée (South-East, department : Côte d'Or). This site is located near the vineyards of 'Côte de Nuits' (Burgundy). Ground water is a free aquifer mainly supplied by leaching of rainfall through soil. The soils are filtrating, with a low content of organic matter and a low microbial activity. The deeper layers consist of karstic limestone laying on calcareous and sandy clay. The well, digged out at a depth of 10 meters, is located in a low point and drains all the waters of this area. The volume of the ground water body varied from 14 000 to 75 000 m³ over the period of the study.

A survey was conducted by the local authorities of the Ministry of Agriculture, covering the vineyards of 'Côte d'Or' and 'Côte Chalonnaise'. In this limited area, the vineyards surface represents 10 063 ha and a total of 29.183 tons of amitrole was applied in 1998. Additionally, an amount of 6.5 kg amitrole was applied 10 km around the sampling site, for treatment of non-cultivated areas. In 1999, a total of 13 metric tons of amitrole was applied in the department "Côte d'Or" on 4 400 ha, 991 kg in both districts of Vosne-Romanée and Nuits-Saint Georges, and 151 kg in the protection area of the well. This protection area covers 240 ha of which about 144 are vineyards.

Site 10 : Segonzac (Middle-West, department : Charentes). The sampling site is a spring called Puyrolland, located in the vineyards of 'Cognac'. Soils of this area are karstic and cracked limestones. In 1999, a total amount of 2 565 kg of amitrole was applied around the sampling site on the water supplying area covering 3 321 ha (1 575 ha of vineyards).

Site 11 : Xaintrailles (South-West, department : Lot & Garonne). This site is located in the "Pays d'Albret" in the Valley of Garonne. Vineyard belongs to the AOC Buzet which represents an area of ca 1 780 ha. The soils are calcareous and clayey. Water is sampled from a little spring with a flow of 200 m³/day. Out of 444 ha of agricultural area, about 200 ha are vineyards, and 119 ha are orchards. Approximately 320 kg of amitrole were applied around the sampling site in 1999.

Site 12 : Larroque sur l'Osse (South-West, department : Gers). This site, located in the vineyards of 'Armagnac', corresponds to a re-emergence of ground water from karstic limestone. Vineyards represent 1 878 ha on 32 406 ha of the agricultural area. On the basis of the average ratio observed for the other sites between the amount of amitrole applied and the vineyards area, the amount of amitrole sprayed around Larroque sur l'Osse was estimated to be 3 945 kg in 1999.

Site 13 : Pauhlan (South, department : Hérault). The soils are composed of successive gravelled sandy layers and clay layers. Water is sampled in a well located at a depth of 40-43 meters. In 1999, 12 metric tons of amitrole were applied in the department on 5 840 ha (vineyards and orchards).

Site 14 : Panjas (South-West, department : Lot-et-Garonne). This site is located in the Bas-Armagnac. "Hount grande" is a re-emergent ground water spring near Panjas, in the Basin "MI12". This basin has a surface area of 778 km². The area is mainly cereal cultivation (maize around 30%) and vine cultivation (about 9%), the site is known for pesticides pollution. Around one ton of amitrole each year is sold in the department. The ground water is only 3.5 meter deep. The soils are filtrating : sand called "sables fauves" with a few clay pockets and with molasses contact. The supply of the spring is rain direct infiltration ; the flow is weak (120 m³ per day). The spring supplies about 1 300 inhabitants, and the water treatment consists in a chlorination step. The site has been retained for monitoring because of its environmental characteristics favourable to leaching.

During those campaigns, three analytical methods have been used:

- o HPLC/UV method: consisted in an evaporation followed by a derivatisation of amitrole with sodium nitrite in a slightly acidic medium (formation of a nitroso-derivative) and a quantification of the nitroso derivative by HPLC with an UV detector at 254nm. This method was derived from the method of Soulier et al. (1980). The limit of detection was 0.15 µg/L. In 1996, the analyses were performed by CIRSEE (Centre international de Recherche sur l'eau et l'environnement, Lyonnaise des Eaux, 38 avenue du Président Wilson, 78230 Le Pecq, France). It was then decided not to continue with this method because it could not quantify amitrole at the required level of 0.1 µg/L,
- o HPLC/fluorimetry method: based on the formation of a fluorescent derivative followed by a quantification by HPLC with fluorimetric detection, developed by C.G.I. (Centre de Génie Industriel, Guidel-Plage, 56520 Guidel, France). This method developed in 1997 has been validated by CGI in 1998 and the limit of quantification (LOQ) of this method has been 0.05 µg/L since 1999. From 1997 onwards, all samples were analysed according to this method,
- o HPLC with mass detection developed by HLS (Huntingdon Life Sciences, Eye, IP23 7PX Suffolk, England) can be used to confirm positive results. This method has been validated in 1998 and the LOQ is also 0.05 µg/L.

□ Findings

In 1996, no residues of amitrole were detected in any of the 11 samples (LOQ=0.15 µg/L).

In 1997, no residues of amitrole were detected in any of the 35 samples (LOQ= 0.10 µg/L).

In 1998, no residues of amitrole were detected in any of 35 samples (LOQ=0.10 µg/L), except twice at Vosne-Romanée (case described below).

In 1999, 2000 and 2001, no residues of amitrole were detected above 0.10 µg/L in any sample (LOQ = 0.05 µg/L).

Case of Vosne-Romanée

In 1998, two positive results were observed in ground water sampled at Vosne-Romanée: 1.7 µg/L on 29 May and 0.17 µg/L one month later. Other samples were below the limit of quantification (0.1 µg/L).

These two positive samples were confirmed by the GC/MS method and quantified at 2.06 and 0.22 µg/L, respectively. It was the first time positive results were obtained for amitrole in ground water since the beginning of the monitoring at Vosne-Romanée. After a careful review of the data available about this contamination, it was shown that the peak of amitrole was more than likely attributable to an accidental pollution such as overfilling or emptying a spray tank containing a mixture of three active ingredients (amitrole, diuron and terbuthylazine).

Rainfall data for this site was obtained from the nearest national weather station, Aloxe Corton, located at 12 km from Vosne-Romanée. This climatological data shows that, except a rainy April month in 1998, that two years are representative of the usual climate of Vosne-Romanée. Under the average climatological conditions of year 1999, no amitrole was detected in ground water sampled at Vosne-Romanée. These results confirm that the positive values were due to an accidental pollution.

□ Conclusion

From 1996 to 2001, no amitrole was detected in ground water in any of 206 samples, except two repeated samples in 1998 at one location. Monitoring results of this site in 1999, 2000 and 2001 confirmed the accidental origin of the pollution observed in 1998.

The results obtained in France are supported by those from campaigns performed in Germany by the German authorities, from 1989 up to 1994, in which no amitrole was detected, in any of 251 samples of either ground or surface water.

The results obtained since 1996 suggest that the rapid degradation of amitrole in soil prevents any contamination of ground water by leaching.

□ Comments from RMS

These studies provide interesting results but they are difficult to use for risk assessment purpose since no sufficient data is available. For example, the description of the wells and of their hydrogeological context is very limited. The available information is therefore not sufficient to conclude on the vulnerability of the selected wells. The transfer velocities are not taken into account, and no information on the climatic data was provided, except for the site Vosne-Romanée at which residues were detected.

In addition, the number of wells that are followed is not constant. It can be seen in Table 8.7.4-1 that 2 wells were followed in 1996, 4 in 1997, 7 in 1998, 10 in 1999, 2 in 2000 and 1 in 2001. Except for wells 3, 4 and 9, that has been following during 3 or 4 consecutive years, the others were only followed during 1 or 2 years, therefore, it is difficult to get a clear interpretation of the results. These studies are considered as supplemental information.

WARNING: This document forms part of an EC evaluation data package and should not be read in isolation. Registration must not be granted on the basis of this document.

B.8.11. REFERENCES RELIED ON**Annex II Data and information**

OECD Annex point/reference number	Author(s)	Year	Title Testing Facility Owner / Source (where different from owner) Report No GLP or GEP status (where relevant) Published or not	Data protection claimed yes/no	Owner
KIIA 7.1.1/01	Hall, B.E.	1994	The aerobic degradation of radiolabelled amitrole in soil. Report No: 10526. GLP	Y	NUFARM
KIIA 7.2.1/01 KIIA 7.3.1/02 KIIA 7.8.3/03	Comoretto, L.	2012a	Amitrole – Estimating persistence and degradation kinetics from environmental fate studies on Amitrole. Study No.: NUFkinetic31082012 Not GLP.	Y	NUFARM
KIIA 7.3.1/01	Biever, R.C.	1995	Amizol: A field dissipation study for terrestrial uses. SLI Report #93-10-4999 GLP	Y	NUFARM
IIA 7.4.1/01	Menerling, M.	2012	Adsorption/desorption study Ibacon report n°70821195 GLP Not published	Y	NUFARM
IIA 7.7/01	Feil-Klein, N	2012	Ready Biodegradability of amitrole (XT91) in a manometric test Ibacon project n°70822163 GLP Not published	Y	NUFARM

Annex III Data and information

OECD Annex point/reference number	Author(s)	Year	Title Testing Facility Owner / Source (where different from owner) Report No GLP or GEP status (where relevant) Published or not	Data protection claimed yes/no	OWNER
KIIIA 9.6.1/07 KIIIA 9.7.1/08	Comoretto, L.	2012e	Predicted environmental concentration of Amitrole in groundwater(PECgw), surface water(PECsw) and sediment(PECsed) following application on non crop using HardSPEC 1.4.2. Nufarm Report: NUFHS22072012A GLP Unpublished	Y	NUFARM

KIIIA 9.6.1/08 KIIIA 9.8/07	Comoretto, L.	2012f	Predicted environmental concentration of 1,2,4-triazole in groundwater(PECgw), surface water(PECsw) and sediment(PECsed) following application on non crop using HardSPEC 1.4.2. Nufarm Report: NUFHS22072012B GLP Unpublished	Y	NUFARM
KIIIA 9.8/01	Comoretto, L.	2012k	Predicted environmental concentrations (PEC) of the metabolite 1,2,4-triazole in surface water and sediment (PECsw and PECsed) according to FOCUS surface water scenarios after applications on citrus Nufarm report n°NUFSW19072012A GLP Unpublished	Y	NUFARM
KIIIA 9.8/02	Comoretto, L.	2012l	Predicted environmental concentrations (PEC) of the metabolite 1,2,4-triazole in surface water and sediment (PECsw and PECsed) according to FOCUS surface water scenarios after applications on olives Nufarm report n°NUFSW19072012B GLP Unpublished	Y	NUFARM
KIIIA 9.8/03	Comoretto, L.	2012m	Predicted environmental concentrations (PEC) of the metabolite 1,2,4-triazole in surface water and sediment (PECsw and PECsed) according to FOCUS surface water scenarios after applications on vines Nufarm report n°NUFSW19072012C GLP Unpublished	Y	NUFARM
KIIIA 9.8/04	Comoretto, L.	2012n	Predicted environmental concentrations (PEC) of the metabolite 1,2,4-triazole in surface water and sediment (PECsw and PECsed) according to FOCUS surface water scenarios after applications on orchards Nufarm report n°NUFSW19072012D GLP Unpublished	Y	NUFARM
KIIIA 9.8/05	Bertrand M.	2011f	Predicted environmental concentrations (PEC) of the metabolite 1,2,4-triazole in surface water and sediment (PECsw and PECsed) according to FOCUS surface water scenarios after applications on olive trees, pome and stone fruits and vines Nufarm Report: NUFWS071111 GLP Unpublished	Y	NUFARM